## **Douglas Grier**

# Updated Materials List in Addition to Materials Referenced in Report

**Barbara Smith** 

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#### **Production Materials**

### **Document Description [Bates Range]**

000001 4275674 d Use of Gynemesh PS in Prolapse Surgery Power Point

02.01.2012 Prosima 522 cover letter

02.01.2012 Prosima Postmarket Surveillance Study PS120044; Gynecare Prosima Pelvic Floor Repair Systems

10/12/1990 Letter from FDA re: N16374, Prolene Polypropylene Nonabsorbable Suture

1973 Prolene Mesh Rabbit Study ERF 73-130 - Prolene Mesh- Biological Evaluation in Rabbits

2000 June TVT Surgeons Resource Monograph

2000 TVT Surgeon Monograph

2001 TVT Surgeon's Monograph

2003 Gynemesh PS white paper. Gynemesh PS Early Clinical Experience.

2003 PSE 03-0740 TVT-O Stability Report

2003 TVT-O Design Validation

2004 Gynemesh PS Study Poster - AUGS 2004 San Diego. Lucente V, Hale D, Miller D, Madigan J. A Clinical Assessment of Gynemesh PS for the Repair of Pelvic Organ Prolapse.

2004 TVT-O DHF Index

2005-06 Prof Ed Slides

2006 Biocompatibility Risk Assessment for Laser-Cut Implant of Gynecare TVT

2006 Mar 3 Flatow memo - CPC-2006-0165 Performance evaluation of TVT PROLENE blue Mesh\_ Elongation

Properties of Mechanical Cut verses Laser Cut 2007 Prolift Professional Education Slide Deck

2007 Prolift Surgeon's Resource Monograph

2007 Prolift Surgical Technique Guide

2008 Carey - Vaginal surgery for POP using mesh and a vaginal support device

2008 Prolift Patient Brochure

2009 Zyczynski - AUA Abs 1354 A new operation for vaginal prolapse repair using mesh and a vaginal support device: 1 year anatomic and functional results of an international, multicenter study. J Urol; 181(4) (Suppl), 4.28.2009

2010 TVTO Clinical Expert Report

2011 Singh - ICS Abs 575 Anatomic, functional and ultrasound outcomes after vaginal prolapse surgery using non-anchored mesh

2011 TOPA FDA Rejection Letter dated 02.11.11

2012 Sayer, Hinoul, Gauld (Prosima) - [IUJ] Medium-term clinical outcomes following surgical repair for vaginal prolapse with tension-free mesh and vaginal support device. Int Urogynecol J (2012) 23:487-493

5.15.08 Summary of Safety and Effectiveness - Prolift

6.2.2006 Ethicon Expert Meeting Meshes for Pelvic Floor Repair.

9.22.2011 Letter to surgeons

A Clinical Assessment of Gynemesh PS for the repair of pelvic organ prolapse by V. Lucente, et al.

A Solution-Gynecare TVT Tension-Free Support for Incontinence.

Application FMEA for TVT Classic Doc# FMEA-0000536 Rev.<1>

AUGS Transvaginal Mesh Informed Consent Toolkit

Australian Pelvic Floor Discussion

Benefit Risk Profile of Transvaginal Mesh Products Used for the Treatment of Pelvic Organ Prolapse signed by Piet Hinoul

Benefit Risk Profile of Transvaginal Mesh Products Used for the Treatment of Pelvic Organ Prolapse signed by Piet Hinoul dated 6/21/2012

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#### **Production Materials**

Biocompatibility Risk Assessment Report for GYNECARE GYNEMESH PS PROLENE - Appendix 1: Tabular Summaries....nrl

Biocompatibility Risk Assessment Report for GYNECARE GYNEMESH PS PROLENE - Appendix 2: Brief CV's... (2).nrl

Biocompatibility Risk Assessment Report for GYNECARE GYNEMESH PS PROLENE... (1).nrl

Brigette Fatton Powerpoint Presentation entitled "Complications in Pelvic Floor Dysfunction Surgery: evaluation and management.

C. Linsky Memo re Cytotoxicity Risk Assessment for the TVT (Ulmsten) Device, Aug. 8, 1997, at 1.

Chevron Phillips MSDS (Exhibit T. No. 3137 - 8.9.2013)

Classification Website Intro "An International Urogynecological Association (IUGA/Internation Continence Society (ICS) Joint Terminology and Classification of the Complications Related Directly to the Insertionm of Prostheses (Meshes, Implants, Tapes) & Grafts in Female Pelvic Floor Surgery."

Clinical Evaluation Report - Gynecare Prolift signed by P. Hinoul on 04.26.2013

Clinical Evaluation Report, Gynecare TVT Tension-free Vaginal Tape / Tension-free Vaginal Tape Accessory Abdominal Guide [ETH.MESH.4384126-65]

Clinical Expert Report [ETH.MESH.1784823-28]

Clinical Expert Report [ETH.MESH.222899-909]

Clinical Expert Report Gynecare Prolift +M™ Pelvic Floor Repair System signed by Piet Hinoul dated 9/25/2012 [ETH.MESH.08315779-810]

Corporate Product Characterization Plan, TVT-Laser Cut Mesh. Dated 02/06/2006.

Correspondence between Morgan Liscinsky of FDA & Bloomberg re: Johnson & Johnson Vaginal Mesh Implant.

D00001256-2005 Prolift Ed Gynecare Prolift Pelvic Floor Repair

D00001260-2007 and 2008 Prolift and M Prof Ed

Dear Surgeon Letter from Piet Hinoul and Aaron Kirkemo.

Declaration of Reynaldo Librojo in Support of Motion for Summary

Declaration of Thomas A. Barbolt, Ph.D., DABT, 1981-2011 in Support of Motion for Summary Judgement

Defense 1584 - One Year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device

Defense 2 - Clinical Assessment of Gynemesh PS for the Repair of Pelvic Organ Prolapse

Demonstrative - Ethicon Powerpoint - Almost uniformly, physicians did not express a preference for company name (Engleman trial exhibit)

Demonstrative - Ethicon powerpoint - Next generation slings - evaluating opportunities, considering risks (Engleman trial exhibit)

Demonstrative - Powerpoint - Warning regarding FBR inflammatory response (pgs 18, 22-27)(Engleman trial exhibit)

DEPO.ETH.MESH.00004755 - Guidoin Explant

Document entitled "Delay in Prosima Activities"

Document entitled "Pelvic Floor Repair. Extended Review of Medical Literature."

DX23600-R.1-3 - Prolene Resin Manufacturing Specifications 1.23.03

DX25662.71 - Prolift Design Validation

Email dated 1/17/2010 from Dr. Piet Hinoul to Dr. David Robinson, et al. Re: +M relaxation

[ETH.MESH.01785259-60]

Email dated 1/22/2010 from Scott Jones to Kevin Frost and Tom Affeld re: Summit Agenda/Moderator; cc: Matt Henderson, et al. [ETH.MESH.00817181]

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#### **Production Materials**

Email dated 6/8/2012 from Matt Henderson to Tim Schmid re: 522 Communication Recap [ETH.MESH.04568519]

Email dated 9/3/2009 from Piet Hinoul to David Robinson, et al. re: Prosima Take Away Messages; cc: Peter Meier [ETH.MESH.01237077-79]

Email from Arnaud re: Transient Leg Pain with Mulberry [ETH.MESH.3911390-1]

Email from Dan Smith re: Draft report translated by "Babel fish" http://babelfish.altavista.com/tr

[ETH.MESH.865069-72]

Email from Dan Smith re: NG TVT-O NDP - Outcomes from Kickoff Meeting with Pr. De Leval & Dr. Waltregny [ETH.MESH.2293715-6]

Email from Frost to Globerman, et al. re: prosima usage northeast [ETH.MESH.11538048-49]

Email from Frost to Affeld, et al. re: Sales Rep Training on Prosima 5/18 [ETH.MESH.03895925-26]

Email from Hinoul re: South Africa, TVTO sheaths getting stuck upon removal [ETH.MESH.1210987-95]

Email From Lewis to Mahar, et al. re: How did Dr. Grier's Prosima cases go? [ETH.MESH.00127125-26]

Email from O'Bryan re: GYNECARE TVT Obturator System - FDA [ETH.MESH.6882641-2]

Email from O'Bryan re: ifu [ETH.MESH.3364663-66]

Email from Scott Jones to DL-Ethusso dated 12/15/2009 re: PAGS Leads [ETH.MESH.00662233]

Email from Seppa re: Performance Evaluation of TVT Secur PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920) (4.25.2005)

Email from Seppa re: Performance Evaluation of TVT U PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920) Version 2

Email from Seppa re: Performance Evaluation of TVT U PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920) Version 2 (5.4.2005)

Email from Shalot Armstrong dated 9.1.10 [ETH.MESH.07453752-57]

Email from Shalot Armstrong dated 9.1.10 [ETH.MESH.08918949-52]

Email from Tim Schmid to Chuck Austin dated 6/8/12 re: Prolift +M withdrawal notice [ETH.MESH.04568717-18]

Email from Weisberg re: IFU update [ETH.MESH.3365250-1]

Email from Weisberg re: Mulberry [ETH.MESH.6886410-11]

Email re: 60% Success [ETH.MESH.01776504-10]

Email re: 69% Success [ETH.MESH.00547500-501]

Email re: Alerte TVT Abbrevo (April 3, 2012) [ETH.MESH.03941617-18]

Email re: Alerte TVT Abbrevo (May 10, 2012) [ETH.MESH.05998835-36]

Email re: Faculty & Customer Call Post-FDA Panel Mtg on 9/12 [ETH.MESH.04543334]

Email re: IFU errors [ETH.MESH.02229013]

Email re: Important Laser cut mesh update [ETH.MESH.1809056-58]

Email re: Laser Cut TVT [ETH.MESH.6859834-35]

Email re: Meeting Minutes from April 18 2012 meeting w FDA [ETH.MESH.04476274-75]

Email re: Mesh Fraying Dr. EBERHARD letter [ETH.MESH.7692905-7]

Email re: No RCT for Prosima [ETH.MESH.00592585-87]

Email re: OR Agenda Tunn [ETH.MESH.3922926-28]

Email re: Overstating Success - Less Misleading [ETH.MESH.00594266]

Email re: Performance Evaluation of TVT Prolene Blue Mesh [ETH.MESH.6696411-19]

Email re: Piet explaining why no Ultrapro in Prosima [ETH.MESH.01237077-79]

Email re: Piet explaining why Prosima uses a VSD [ETH.MESH.00580588-89]

Email re: Piet explains PS in Prosima [ETH.MESH.00580711-13]

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#### **Production Materials**

Email re: Piet following 2011 Ad Com [ETH.MESH.04568448]

Email re: Piet re Problem with posterior inserter [ETH.MESH.02579701-06]

Email re: Piet's response to 522 FDA refusal [ETH.MESH.05987605-06]

Email re: Piet's response to 522 FDA refusal clean [ETH.MESH.04548975]

Email re: Piet's takeaways from 2011 FDA meeting [ETH.MESH.04556236]

Email re: Prof. de Leval - TVT Abbrevo (April 2, 2012) [ETH.MESH.04938298-99]

Email re: Prosima Jan 2007 Updated [ETH.MESH.00455676-77]

Email re: Smelly VSDs [ETH.MESH.00591563-65]

Email re: Stop communicating over email [ETH.MESH.00594455]

Email re: TVT Laser Cut Mesh [ETH.MESH.525573]

Email re: TVT Laser Mesh info [ETH.MESH.442825-26]

Email re: TVT Meeting with Agency [ETH.MESH.524746-48]

E-mail string dated 1/21/2010, top one from Piet Hinoul to Clifford Volpe and David Robinson re: dimensions of the PROSIMA implant [ETH.MESH.00851319-21]

E-mail string dated 11/3/2010 re: neo clinical trial. Piet Hinoul: "Each individual study does not contribute to the success of those products [ETH.MESH.00856579-82]

Email string dated 3/25/2010, top one from Piet Hinoul to Paan Hermansson re: key message for Prosima launch [ETH.MESH.00580588-89]

Email string dated 5/12/2011, top one from Kevin Frost to Benjamin Bouterie re: Dr. Bedestani; cc: Stacy Hoffman [ETH.MESH.03466382-83]

Email string re: Revised write up of the DeLeval and Waltregny visit

Email string re: Ultrapro vs Prolene Soft Mesh

Email string, top one from Gary Pruden to David Robinson, et al. re: article entitled: Vaginal repair with mesh no better than colporrhapy for pelvic organ prolapse.

ETH.MESH.00000172 - 8/25/11 Email from Marie Hobson to Kevin Frost attaching registration list for call

ETH.MESH.00000173 - 8/25/11 Registration list for 8/25/11 call

ETH.MESH.00001314 - Gynecare Prolift Pelvic Floor Repair System

ETH.MESH.00001595-606 - Reisenauer C. Anatomical conditions for pelvic floor reconstruction with polypropylene implant and its application for the treatment of vaginal prolapse. Eur J Obstet Gynecol Reprod Biol 2006

ETH.MESH.00003895 - Continence Health and Pelvic Floor Advisory Board Opening Comments for Renee

ETH.MESH.00012009-074 - Cosson M. Clinical assessment of feasibility, complications and effectiveness at twelve months, three years and five years of the TVM technique for genital prolapse(French 1 year CSR)

ETH.MESH.00012009-089 - Clinical Study Report: Clinical assessment of feasibility, complications and effectiveness at twelve months, three years and five years of the TVM technique for genital prolapse.

ETH.MESH.00012090-163 - Robinson D. Clinical assessment of the TVM technique for treatment of genital prolapse. Final Report of 12-month evaluation. (US 1 year CSR)

ETH.MESH.00013529-534 - Prolift+M IFU

ETH.MESH.00016032-039 - Kohli N. Augmenting pelvic floor repairs. 2006 Supplement to OBG Management

ETH.MESH.00017362-368 - Elmer C, et al. Histological inflammatory response to transvaginal polypropylene mesh for pelvic reconstructive surgery. J Urol (2009); 181(3): 1189-95.

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#### **Production Materials**

ETH.MESH.00017553-560 - Tunuguntla, H. Female Sexual Dysfunction Following Vaginal Surgery: A Review.

Journal of Urology 2006; 175: 439-446

ETH.MESH.00018344-479 - Gynemesh PS Prof Ed Slide Deck 2007 000001 168547 d

ETH.MESH.00018382 - 2007 Powerpoint GYNECARE GYNEMESH\* PS Nonabsorbable PROLENE\* Soft Mesh in the Treatment of Pelvic Organ Prolapse\_DX24191

ETH.MESH.00018382 - Powerpoint: Gynecare Gynemesh PS Nonabsorable Prolene Soft Mesh in the Treatment of Pelvic Organ Prolapse

ETH.MESH.00019117-121 - Letter from Scott H. Jones to Price St. Hilaire re: Prosima US Launch Plan; cc: Renee Selman, et al.

ETH.MESH.00019117-121 - Prosima Launch Memo with Prepceptor Info from Hilaire

ETH.MESH.00020763

ETH.MESH.00020764

ETH.MESH.00028555-556 (Adkins Trial Exhibit P2669)

ETH.MESH.00031323 - Memo to Customer from Sean M. OBryan

ETH.MESH.00031324-325 - Letter to Gregory Jones from Celia M. Witten

ETH.MESH.00064002-004 - Email string, top one from Judith Gauld to Scott Jones re: US preceptors for Prosima.

ETH.MESH.00064054 - Gynecare Prosima ™ Pelvic Floor Repair System - Global Launch Strategy

ETH.MESH.00064138-139 - Document entitled "PROSIMA Critical Success Factors."

ETH.MESH.00071755 - Prosima - Apical Support Learning Guide

ETH.MESH.00071794 - Email re: TVT IFUs on tape extrusion, exposure and erosion

ETH.MESH.00076167 - Letter from Bryan Lisa to Dan Smith re: Prosima Product Release Authorization; cc: Stephanie Kute, Jennifer Paine.

ETH.MESH.00076167 - Prosima Product Release Authorization (July 2007)

ETH.MESH.00076710-790 - Clinical Study Report. Evaluation of Prosima for Pelvic Organ Prolapse. Protocol Number: 300-06-005. "A Prospective, Multi-centre Study to Evaluate the Clinical Performance of Gynecare Prosima Pelvic Floor Repair System as a Procedure for Pelvic Organ Prolapse."

ETH.MESH.00077073-093

ETH.MESH.00077094-111

ETH.MESH.00077395

ETH.MESH.00077739 - Prosima Story

ETH.MESH.00078114-115 - Memo to Prosima Regulatory File. Minutes from Teleconference with FDA for Prosima 510(k).

ETH.MESH.00082651-654 - Email string, top one from Marcus Carey to J. Meek, D. Robinson, P. Hinoul, et al. re: Technical feedback on Prosima.

ETH.MESH.00083812-814

ETH.MESH.00086463-465 - E-mail from Piet Hinoul to Zeb Viana, et al. regarding TR: PROSIMA TAKE AWAY MESSAGES; cc: Bart Pattyson, et al.

ETH.MESH.00093526-544

ETH.MESH.00093991

ETH.MESH.00108120-121 - Email string, top one from Douglas Grier to Lissette Caro-Rosado, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattyson.

ETH.MESH.00125373 - Email string, top one from Tom Eagan to Erin Haggerty re: Dr. Sepulveda.

ETH.MESH.00126755-757 - Email string, top one from M. Yale to J. Paine, et al. re: Draft FDA response on Prolift+M for input

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### **Production Materials**

ETH.MESH.00127103 - Email from Greg prine to Scott Jones, Jonathan Meek re: Prosima Road Show; cc: Lesley
Fronio and Kevin Mahar.
ETH.MESH.00129102 - Suggested Remarks - Incontinence and Pelvic Floor Summit What a Difference a Decade
Makes
ETH.MESH.00131058-095
ETH.MESH.00131149-151 - Email string, top one from Stephanie Grupe to Kevin Mahar re: Prosima Global
Launch Team.
ETH.MESH.00134794-795 - Jason Hernandez email to Nicholas Antoun et al dated 02.27.2009 attaching TVT
World Board meeting presentation (Engleman/Adkins Trial Exhibit P0086)
ETH.MESH.00142622-624
ETH.MESH.00143784-785
ETH.MESH.00144210
ETH.MESH.00144211
ETH.MESH.00144270-278
ETH.MESH.00144449 - Letter from David Robinson re: decision to delay preceptor training activities for Prosima
(not signed).
ETH.MESH.00144721-723
ETH.MESH.00145547-548
ETH.MESH.00145551
ETH.MESH.00145555
ETH.MESH.00147320-325
ETH.MESH.00147904
ETH.MESH.00148901-902
ETH.MESH.00153967 (Adkins Trial Exhibit P0127)
ETH.MESH.00155903-905
ETH.MESH.00155903-906
ETH.MESH.00155906
ETH.MESH.00155975
ETH.MESH.00156178-181
ETH.MESH.00156855-856
ETH.MESH.00156906-908
ETH.MESH.00156909-952
ETH.MESH.00156954-955
ETH.MESH.00158065-067
ETH.MESH.00158083-084
ETH.MESH.00159266-369 - Gynemesh PS, Prolene Soft Mesh in the treatment of POP – Pelvic Floor Surgery and
Anatomic Dissection Lab
ETH.MESH.00159410-411
ETH.MESH.00159432-433
ETH.MESH.00159434-465
ETH.MESH.00159884-986
ETH.MESH.00160615-625
ETH.MESH.00166552
ETH.MESH.00166553-555
ETH.MESH.00167104-110 - 2006 Apr 19 - Laser Cut Mesh for Gynecare TVT- CER Laser Cut Mesh
ETH.MESH.00167684-685
ETH.MESH.00169300-303

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#### **Production Materials**

ETH.MESH.00220335-336 - 12.2.1999 Memo re: Biocompatibility Risk Assessment for Soft Prolene Mesh.

ETH.MESH.00259305 - 2003 TVT-O Clinical Strategy

ETH.MESH.00262015-016 - Dan Smith Email Plaintiffs Exhibit 2067

ETH.MESH.00271215-216 - Email from J. Meek to multiple recipients e: Pre-Reading for Prolift+M: Internal Use Only. Not Copy Reviewed or For Distribution

ETH.MESH.00273967 - Email from Clifford Volpe to Scott Jones re: slides for Pelvic Floor Summit.; Powerpoint: R&D Perspective - The Journey from Prolift to Prolift +M.

ETH.MESH.00274015 - Krofta Presentation - One year prospective follow-up of the TVT-S Procedure for treatment of stress urinary incontinence (Engleman Trial Exhibit P0238)

ETH.MESH.00281482-484 - Aaron Kirkemo email to Harel Gadot, et al., re Prosima feedback (Engleman Trial Exhibit P0241)

ETH.MESH.00295355

ETH.MESH.00303310-313 - Memo from Dan Lamont to Gynecare Prosima Risk Management Report (RMR-0000029) re: Pelvic Floor Product(s) Complaint Review for Gyneacre Prosima Risk Management. (March 2007)

ETH.MESH.00308094 - 2006 TVT-Secur (2629 2006-07-12)

ETH.MESH.00310205 - Product Quality Issue re: Prosima signed by Mark Yale.

ETH.MESH.00310206 - Letter from David Robinson re: decision to delay preceptor training activities for Prosima (not signed).

ETH.MESH.00316849-850

ETH.MESH.00318930 - (Draft) Letter from David Robinson re: delay in preceptor training activities for Prosima.

ETH.MESH.00318934 - Document entitled " Delay in Prosima Activities."

ETH.MESH.00324109 - Carolyn Brennan email to Mark Yale dated 11.02.2006 re TVT-S difficulties with insertion of device (Engleman/Adkins Trial Exhibit P0274)

ETH.MESH.00326842-846 - Catherine Beath email to Sheri McCoy and Renee Selman dated 11.05.2007 re urgent meeting with Australian \_\_\_\_\_\_ to discuss TVT Secur performance - includes email from Aran Maree dated 11/2/2007 re Australian launch of TVT S (Engleman/Adkins Trial Exhibit P0286)

ETH.MESH.00326911 - Ethicon Delayed Prosima Launch by Two Years

ETH.MESH.00327060-063 - Robinson email (Dr. Aran Maree) chain dated 11.12.2007 re Dr. Frazier's (Australia) opinions re TVT-S (Engleman/Adkins Trial Exhibit P0290)

ETH.MESH.00328895-901 - David Robinson email to Mark Yale and Daniel Lamont dated 03.03.2008 re quality issue with a batch of gynemesh (Engleman/Adkins Trial Exhibit P0292)

ETH.MESH.00329474-509 - Project Mint Design Review

ETH.MESH.00335084-085 - Email from Daniel Lamont to Sungyoon Rha, et al. re: Mint Functional Strategies.

ETH.MESH.00349226-237 - May 26, 2000 Ethicon Memo to P. Cecchini RE: Review of Biocompatibility Data on the Tension Free Vaginal Tape (TVT) System for Compliance to FDA G-95/ ISO 10993/ EN 30993

ETH.MESH.00349228 - 1997 Cytotoxicity Risk Assessment for the TVT (Ulmsten) Device (Barbolt) - includes Prolene NDA studies

ETH.MESH.00352889-909

ETH.MESH.00353020-037

ETH.MESH.00354732

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#### **Production Materials**

ETH.MESH.00365412-414 - June 14, 2007 Memo RE: ADDENDUM: Post - Launch Complaint Review for the PROLIFT\* Pelvic Floor Repair System

ETH.MESH.00365960-965 - Gynecare TVT Secur System Procedural Pearls & Frequently Asked Questions.

ETH.MESH.00369995

ETH.MESH.00369999 - 2008 TVT-Secur (2008-135)

ETH.MESH.00370315 - Prosima Training Deck 1

ETH.MESH.00370421

ETH.MESH.00371595-903 - Prosima 510K and Clearance letter

ETH.MESH.00372564-568

ETH.MESH.00372664-671 - Letter from B. Lisa to J. Dang re: K071512 S04. (02.21.2008)

ETH.MESH.00373310-388 - Gynecare TVT Tension-Free Support for Incontinence: General Profession Education Deck.

ETH.MESH.00393045-046 - TVT-O Procedural Steps

ETH.MESH.00394849 - Gynemesh PS Panel Powerpoint - Drs. Robinson, Miller, Winkler, England

ETH.MESH.00395374-380 - Scientific Advisory Panel on Pelvic Floor Repair Preliminary Minutes Chicago, IL, June 22. 2001

ETH.MESH.00397327

ETH.MESH.00397674

ETH.MESH.00405513-514

ETH.MESH.00409158 - (Official) Letter from David Robinson re: delay in preceptor training activities for Prosima.

ETH.MESH.00418855-856 - Email string, top one from Andrew Meek to Jonathan Fernandez, et al. re: Prosima Preceptor Recommendation Form; cc: Kevin Frost, et al.

ETH.MESH.00424374-375 - Email string, top one from Jonanthan Fernandez ro Rhonda Peebles re: remaining 2010 labs; cc: Robert Zipfel.

ETH.MESH.00426441 - Email from Kevin Frost to Robert Zipfel, et al. re: Prosima 2-year slide deck; cc: Paul Parisi.

ETH.MESH.00442129

ETH.MESH.00455676-677 - Email from Allison London Brown to Ophelie Berthier, et al. re: Prosima Jan 2007 update; cc: Bob Roda, et al.

ETH.MESH.00461576 - 10.23.2006 letter to EWHU field sales force

ETH.MESH.00467320 - Email string, top one from Andrew Meek to Bart Pattyson, Paul Parisi re: November Lab.

ETH.MESH.00484929

ETH.MESH.00495796-798 - Email string, top one from Jennifer Paradise to Melissa Doyle, et al. re: Prof Ed through Tele-Mentoring; cc: Paul Parisi, et al.

ETH.MESH.00510562-563 - Email string, top one from Kevin Frost to DL-ETHUSSO EWHU DMs, et al. re: 1st Prosima Virtual Round Table Tomorrow; cc: Matt Henderson, et al.

ETH.MESH.00516424-427

ETH.MESH.00520649-722 - 2006 US TVM 12 Month Clinical Report

ETH.MESH.00523617 - 2007 TVT-Secur Critical Steps (2007-4144)

ETH.MESH.00523942 - Waltregny 2005 ICS Presentation

ETH.MESH.00526473-474 - Allison Brown Email re-Laser-cut Mesh

ETH.MESH.00541379-380 - Mesh Fraying for TVT Devices

ETH.MESH.00541391

ETH.MESH.00541708-709 - Document entitled "Notes from Competitive Ad Board."

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#### **Production Materials**

ETH.MESH.00541873 - Chart listing Proposed Lab Scheduling for August 4th.

ETH.MESH.00541876-878 - Email string, top one from Bart Pattyson to David Robinson, et al. re: ICS/IUGA Cadaver Lab - Monday Aug 23.

ETH.MESH.00542347-348 - Calendar appointment re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones and Schlafstein.; created by Robert Zipfel.

ETH.MESH.00542463 - Powerpoint: Gynecare Prosima ™ Pelvic Floor Repair System: 2-Year Clinical Data

ETH.MESH.00547021 - Ethicon Women's Health & Urology "Welcome Letter" to the EWH&U Pelvic Floor Repair Advisory Board Meeting.

ETH.MESH.00547036-037 - Email string, top one from Bart Pattyson to Jaime Sepulveda, et al re: Prosima (&Elevate) Advisory Board - Jan 8th - Baltimore; cc: Piet Hinoul, et al.

ETH.MESH.00547500-001 - P. Hinoul email 11.2009

ETH.MESH.00573815 - Powerpoint: Two Year Clinical Outcomes after Prolapse Surgery with Non-Anchored Mesh & Vaginal Support Device (Gynecare Prosima\* Pelvic Floor Repair System) June 2010.

ETH.MESH.00573860-878 - (Draft) Sayer, T., et al. "Medium-term Clinical Outcomes Following Surgical Repair for Vaginal Prolpase with Tension-free Mesh and Vaginal Support Device."

ETH.MESH.00575257 - Abbrevo laser cut vs. mechanically cut - notes from meeting with de leval - inappropriate

ETH.MESH.00575270-273 - Jean de Leval Email Re: DSCN3332.JPG May 30, 2009

ETH.MESH.00575580-581 - Email string, top one from Jonathan Meek to Piet Hinoul, Colin Urquhart and Judi Gauld re: Prosima anterior compartment result.

ETH.MESH.00575634-635 - ICS 2009 Abstract Form. "Surgery for Pelvic Organ Prolapse Using Mesh Implants and a Vaginal Support Device: Analysis of Anatomic, Functional and Performance Outcomes from an International, Multicentre Study."

ETH.MESH.00575818-820 - PX0198 - Piet email re Prolift

ETH.MESH.00578081-083 - Email string, top one from Piet Hinoul to Paan Hermansson re: Prosima Post launch communication.

ETH.MESH.00578550 - (Draft) Sayer, T., et al. "Two Year Clinical Outcomes after Prolapse Surgery with Non-Anchored Mesh and Vaginal Support Device."

ETH.MESH.00578621 - Dr. Piet Hinoul's TVT Secur Literature Analysis; TVT Secur CER 2013

ETH.MESH.00579296 - Powerpoint: Anatomic and Functional Outcomes of 2 Pelvic Floor Repair Systems Studied in Moderate and Severe Prolpase Patients.

ETH.MESH.00580588-589 - Email string, top one from Piet Hinoul to Paan Hermansson re: key message for Prosima launch

ETH.MESH.00584811-813 - Email string re-Ultrasonic Slitting of Prolene Mesh for TVT

ETH.MESH.00584846-847 - (05.10.2004) Email string, top one from Gene Kammerer to Mora Melican, et al. re: Mesh for TVM.

ETH.MESH.00590896-897 - Piet Hinoul Email 3.11.09

ETH.MESH.00592224-229 - E-mail chain from Jonathan Meek to otehrs in regards to Technical Feedback on Prosima

ETH.MESH.00594266 - P. Hinoul email to Affeld 11.2009 re success rates

ETH.MESH.00594528 - Email from Aaron Kirkemo to Piet Hinoul, David Robinson and Judi Gauld re: Prosima commerical claims of 92.3% above the hymen.

ETH.MESH.00595468-470 - Goldman H, FitzGerald M. Opposing Views: Transvaginal Mesh for Cystocele Repair. J Urol (2010) 183: 430-432.

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#### **Production Materials**

ETH.MESH.00595889-890 - Email string, top one from Kevin Frost to Aaron Kirkemo re: Prosima presentation; cc: Tom Affeld.

ETH.MESH.00604183-186 - Email string, top one from Piet Hinoul to Judi Gauld and Colin Urquhart re: PISQ, and score when unable to have sex.

ETH.MESH.00631782-784 - FDA Letter re: K063562 Gynecare Prosima

ETH.MESH.00637343 - 2004 ETHICON Product Development Process - Gynemesh PS

ETH.MESH.00642325-331 (Adkins Trial Exhibit P0429)

ETH.MESH.00658177-198 - Surgeons Resource Monograph

ETH.MESH.00658421-429

ETH.MESH.00662233-234 - DX24786 - Zyczynski PAGS Convention

 ${\sf ETH.MESH.00679637-640-Email\ string,\ top\ one\ from\ Zenobia\ Walji\ to\ Ron\ Naughton,\ et\ al.\ re:\ Prolene\ Soft}$ 

Mesh '05 proposed pricing; cc: Kevin Maher, et al.

ETH.MESH.00687819-822 - Email string re-Laser cut mesh

ETH.MESH.00747864-874 - Gynemesh PS DDSA (rev. 2 - Feb. 2005)

ETH.MESH.00759327-335 - Document entitled "Experience what's new in incontinence and pelvic floor repair."

2010 ICS IUGA Executive Agenda

ETH.MESH.00776993-7000 - Prosima Sales Aid

ETH.MESH.00791497 - Email re Prosima Brochure and DVD

ETH.MESH.00791766 - TVT-Abbrevo Physician Survey Results (January 20, 2011)

ETH.MESH.00800521-522 - Email string, top one from Kenneth Pagel to Melissa Doyle re: presentation access.

ETH.MESH.00806974-975 - Email from Lissette Caro-Rosado to Jaime Sepulveda, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattyson, et al.

ETH.MESH.00807570 - Revised Chart listing Proposed Lab Schedule

ETH.MESH.00807772-774 - Email String, top one from Bart Pattyson to Hugo Ye re: ICS-IUGA - Cadaver Lab & Ask the Expert Update; cc: Ping Li, et al.

ETH.MESH.00807972-973 - Email string, top one from Bart Pattyson to Tommaso Santini, et al. re: US Surgeon; cc: Tom Affeld.

ETH.MESH.00808121-122 - Email from bart Pattyson to Jaime Sepulveda et al. re: Prosima (&Elevate) Advisory Board - Jan 8th - Baltimore; cc: Piet Hinoul.

ETH.MESH.00817181 - Email from Scott Jones to Kevin Frost and Tom Affeld re: Summit Agenda/Moderator; cc: Matt Henderson, et al.

ETH.MESH.00820634 - Invitation to participate in Gynecare Prosima Virtual Round Table

ETH.MESH.00826114 - 2005 Dec 5 D. Robinson email regarding voiding and Prolift

ETH.MESH.00832749-754 - Risk Management Report: Prosima Pelvic Floor Repair Kit

ETH.MESH.00833948-949 - Email from David Robinson to Jessica Shen re: Prosima Study.

ETH.MESH.00834910-911 - Email string, top one from David Robinson to Price St. Hilaire, et al. re: Prosima Strategic Council; cc: Kevin Mahar.

ETH.MESH.00840886-887 - Calendar appointment re: Updated: TVT Secur Preceptor Roundtable Forum; created by Dharini Amin.

ETH.MESH.00843043 - Email from David Robinson to Jacqutin Bernard, Judith Gauld and Jonathan Meek re: cancellation of scheduled Prosima training.

ETH.MESH.00848020-21 - 2006 Jan 27 D. Robinson email regarding voiding and Prolift

ETH.MESH.00849014-017

ETH.MESH.00850335-336 Email string, top one from David Robinson to Stephanie Kute, Patrice Napoda re: Prosima FDA Review and IFU; cc: Price St. Hilaire, Dan Smith.

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#### **Production Materials**

ETH.MESH.00851319-321 - Email string, top one from Piet Hinoul to Clifford Volpe and David Robinson re dimensions of the PROSIMA implant

ETH.MESH.00857821 - Top Ten Reason to pursue Gynecare TVT Obturator System

ETH.MESH.00858080-081 - Perry Trial - Plaintiff's Exhibit 2313

ETH.MESH.00858096-097 - Gynecare R&D Monthly Update - May

ETH.MESH.00858175-176 - Mulberry Weekly Meeting MINUTES for 6.3.03

ETH.MESH.00858252-253 - 2004 Memo from London Brown to Dan Smith re Mechanical Cut vs. Laser Cut Mesh Rationale (Adkins Trial Exhibit P0542)

ETH.MESH.00863391 - T-366 - Dan Smith email - particle loss

ETH.MESH.00870466-476 - (06.02.2006) Ethicon Expert Meeting: Meshes for Pelvic Floor Repair.

ETH.MESH.00874445 - TVT-S Quality Board powerpoint (Engleman Trial Exhibit P0581)

ETH.MESH.00895089-091 - Email string, top one from Kevin Frost to Vincenza Zaddem re: Prosima in R&D Study.

ETH.MESH.00916799 - Project MINT Charter Review

ETH.MESH.00921692-694 - Email string, top one from Tom Affeld to Scott Jones, et al. re: NEO #2, 3, 4 Lab Nominations; cc: Vincenza Zaddem.

ETH.MESH.00922443-446 - Email string, top one from P. St. Hilaire to B. Lisa, et al. re: Bidirectional elasticity statement

ETH.MESH.00925065-067 - Email string, top one from Joshua Samon to Vincenza Zaddem re: Mint Value Proposition; cc: Duan Broughton.

ETH.MESH.00991195-257

ETH.MESH.00993273 - 2006 (2091 2006-02-01) TVT-O Summit Presentation by Raders and Lucente

ETH.MESH.00993273 - TVT Obturator Anatomic Considerations Clinical Update: Special Considerations, Complications.

ETH.MESH.00997751 - TVT Secur CER 2005 Eth.Mesh.00997751

ETH.MESH.01000731-735 - David Robinson email to Axel Arnaud and Dan Smith dated 12.19.2006 re TVT-S Cookooks (Engleman/Adkins Trial Exhibit P0619)

ETH.MESH.01075187-215

ETH.MESH.01128679-698 - 2007 TVT-Secur Procedural Steps (TVTS007)

ETH.MESH.01130563-564

ETH.MESH.01130566-568

ETH.MESH.01130567

ETH.MESH.01136239-240 - Email string, top one from Lissette Caro-Rosado to Ad Board Members re: EWH&U Pelvic Floor Repair Ad Board 1-8-11; cc: Tom Affeld, et al.

ETH.MESH.01154031-037 - Clinical Expert Report - Gynemesh Prolene Soft

ETH.MESH.01189392 - Summary of sheep and human cadaver labs for development of the GYNECARE TVT SECUR System

ETH.MESH.01189423 - TVT Secur CER 2006

ETH.MESH.01198058 - (Draft) Zyczynski, H., et al. "One year clinical outcomes after prolapse surgery with non-anchored mesh and vaginal support device."

ETH.MESH.01200286 - Powerpoint: Gynecare Prosima: Overview.

ETH.MESH.01201973 - Propsed Lab Schedule (2nd Revision)

ETH.MESH.01202189 - Stale Kvitle Email regarding Mini Me follow up from our visit May 20, 2009

ETH.MESH.01202190-191 - David Waltregny Email Re: Mini Me follow up from our visit May 21, 2009

ETH.MESH.01203957-997 - The future of surgical meshes-the industry's perspective

ETH.MESH.01212972 - Hinoul presentation Incontinence Overview

ETH.MESH.01219542-548 - Review of Surgeon Responses of VOC Questionnaire

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#### **Production Materials**

ETH.MESH.01220135-145 - Email string re-New Standards for Urethral Slings

ETH.MESH.01222075-079 - Elongation characteristics of Laser Cut PROLENE Mesh for TVT. 3.6.2006

ETH.MESH.01228079-084 - Nilsson Podcast Transcript

ETH.MESH.01237077-079 Email from Piet Hinoul to David Robinson, et al. re: Prosima Take Away Messages; cc: Peter Meier.

ETH.MESH.01238454-456 - Email string re-TVTO length

ETH.MESH.01244824-826 Email string, top one from Aaron Kirkemo to Cyrus Guidry re: response letter to editor, Lewis Wall.

ETH.MESH.01261962 - TVT-O Summit by Raders, Rogers, Lucente (2005-1819)

ETH.MESH.01264260 - Prolift +M Piet Hinoul Pelvic Floor Meeting Nderland Utrecht, May 7, 2009

ETH.MESH.01271289-301 - TVT with Abdominal Guides Early Clinical Experience

ETH.MESH.01274741-743 - Use of UltraPro Mesh for Pelvic Organ Prolapse (POP) Repair through a Vaginal Approach.

ETH.MESH.01279975-976 - (P041566) Email from Gadot re: Next step in SUI sling (Adkins Trial Exhibit P0686)

ETH.MESH.01310817-829

ETH.MESH.01317508-613 - TVT Factbook DHF - Revised 05.14.2001

ETH.MESH.01320328-333

ETH.MESH.01320351-367

ETH.MESH.01411037-039 - Prosima Study Results

ETH.MESH.0141137-039 Document re: summary of changes in mesh implant from Project Mint to final production.

ETH.MESH.01428106-112 - Carvigni, M. The use of synthetics in the treatment of pelvic organ prolapse. Curr Opin Urol 2001; 11: 429-435.

ETH.MESH.01593930-942 - Prosima Clinical Expert Report (not signed or dated).

ETH.MESH.01595614-753 - Prolift +M IFU

ETH.MESH.01612323-333

ETH.MESH.01613143-146

ETH.MESH.01638150 - Powerpoint: Gynecare Prosima ™ Pelvic Floor Repair System Backrgound; Halina Zyczynski, M.D.

ETH.MESH.01678340 - Email from Andrew Meek to Melissa Doyle et al. re: Approved Prosima Receptors.

ETH.MESH.01687850 (Adkins Trial Exhibit P4127)

ETH.MESH.01707963 - Ethicon Women's Health & Urology "Welcome Letter" to the EWH&U Pelvic Floor Repair Advisory Board Meeting.

ETH.MESH.01708116-117 - Email string, top one from Bart Pattyson to Georgia Long re: TVT Abbrevo and Prosima training; cc: Elizabeth Kolb, Andrew Meek.

ETH.MESH.01708180 - Chart listing financial information re: preceptors.

ETH.MESH.01708190 - Chart listing financial information re: preceptors.

ETH.MESH.01730626-629 - Email string, top one from Dr. Antar to Bart Pattyson re: Prosima presentation.

ETH.MESH.01733531-535 - Kasturi, S. Pelvic magnetic resonance imaging for assessment of the efficacy of the Prolift system for pelvic organ prolapse. Am J Obstet Gynecol 2010; 203: 1.e1-1.e5

ETH.MESH.01739544 - TVT Secur CER 2010

ETH.MESH.01743909

ETH.MESH.01752532-535 - Jurgen Trzewik memo re mesh design argumentation issues (Engleman/Adkins Trial Exhibit P0705)

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#### **Production Materials**

ETH.MESH.01758770-801 - TVT Secur Quality Board powerpoint (Engleman/Adkins Trial Exhibit P0706)

ETH.MESH.01775482 - Prosima letter delying launch

ETH.MESH.01782114-115 - (05.03.2006) Email string, top one from David Robinson to Carolyn Brennan re: Suzette email discussing problems with Prolift.

ETH.MESH.01782783-785 - (02.02.2006) Notes from meeting with Dr. V. Lucente and Dr. M. Murphy (Allentown, PA) to discuss Prolift RCT.

ETH.MESH.01782850-852 (Adkins Trial Exhibit P0716)

ETH.MESH.01784823-828 - Clinical Expert report-Laser Cut Mesh

ETH.MESH.01785259-260 - Email string re: +M relaxation

ETH.MESH.01803816-818 - Summary re: Project Mint

ETH.MESH.01804533-535 - 2003 TVT-O IFU Verification by surgeons

ETH.MESH.01805965

ETH.MESH.01808311-318 - (P041370) Trip Report from Michael Tracey, Principal Engineer -TVT-O de Leval study

ETH.MESH.01809080-081 - Becky Leibowitz email to Paul Parisi and Dan Smith dated 12.14.2004 re comparison of laser-cut and machine-cut TVT mesh to meshes from competitive devices (Engleman/Adkins Trial Exhibit P0732)

ETH.MESH.01809082-083 - Memo re: VOC on new laser cut TVT mesh

ETH.MESH.01813259; ETH.MESH.02180759-61 - Email string with attachment re-Jeans Ideas.

ETH.MESH.01813975-978 - Email string re-FDA Prep-Plaintiff's Exhibit 460

ETH.MESH.01821586-587 Email from Allison London Brown to Ophelie Berthier, et al. re: Prosima November update; cc: Bob Roda, et al.

ETH.MESH.01822361-363 - Dan Smith Email regarding TVT Secur leading to less retention October 18, 2006

ETH.MESH.02001398-404 - Gynecare Prolift IFU (English Only)

ETH.MESH.02001398-473

ETH.MESH.02010349-362 - Prosima Clinical Expert Report signed by David Robinson

ETH.MESH.02017152-158 - (02.23.2007) Ethicon Expert Meeting: Meshes for Pelvic Floor Repair.

ETH.MESH.02020023-024 - Prosima ISO cytotoxicity biocompatibility

ETH.MESH.02026591-595 - MSDS-c4001 Polypropylene Homopolymer

ETH.MESH.02050884-909 - Prosima Key Procedural Steps

ETH.MESH.02059150-151 - May 24, 2006 Memo RE: First Post - Launch Complaint Review for the PROLIFT\* Pelvic Floor Repair System

ETH.MESH.02066770-771

ETH.MESH.02090196-209 - Plaintiff's Exhibit 4085-04.15.2008

ETH.MESH.02092919-921 - Prosima Clinical Strategy

ETH.MESH.02105223 (Adkins Trial Exhibit P0784)

ETH.MESH.02105765-771

ETH.MESH.02114615-616 - Email string, top one from Libby Lewis to Donna Abely, et al. re: Remaining 2010 labs.

ETH.MESH.02124768-769

ETH.MESH.02128955 - 2004 Assessment of the Inside Out Transobturator Approach to implant a Prolene Mesh - Clinical Expert Report

ETH.MESH.02136060-073 - Gynecare TVT Secur system design validation report (product) (Engleman Trial Exhibit P0789)

ETH.MESH.02136955 - DeLeval meeting re TVT Abbrevo development

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**Production Materials** ETH.MESH.02148446-459 - Klosterhalfen, Junge, Klinge. The lightweight and large porous mesh concept for hernia repair (Engleman Trial Exhibit P0791) ETH.MESH.02156379-380 ETH.MESH.02211890 - Test Report ETH.MESH.02211912 - Annex 11: Porosity test on finished product - pelvic floor mesh. ETH.MESH.02215374-375 - Jacquetin B. Prolene Soft (Gynecare) Mesh for Pelvic Organ Prolapse Surgical Treatment: A Prospective Study of 264 Patients. Abstract 767 ETH.MESH.02215565-567 - Email from Scott Ciarrocca to multiple recipients re: a message from Barbara Schwartz re: Prolift (01.02.2005). ETH.MESH.02217343-344 ETH.MESH.02219584 - Scion PA/SUI Treatment Unmet Needs - Exploratory Research, Presented 22 January 2010 ETH.MESH.02229051 - cover sheet Biomechanics ETH.MESH.02229051 - Video: "Biomechanics" ETH.MESH.02229054 - cover sheet What to expect ETH.MESH.02229054 - Video: "What to Expect" ETH.MESH.02229055 - cover sheet VSD case series ETH.MESH.02229055 - Video: "VSD Case Series 1" ETH.MESH.02229057 ETH.MESH.02229059 - Abbrevo placement ETH.MESH.02229063 - Secur placement.wmv ETH.MESH.02229064 - TVT-O placement ETH.MESH.02232685 - Marketing: "Your Proof: Her dance class." ETH.MESH.02232773-801 ETH.MESH.02232854-874 - Prolift+M - Advanced User Discussion ETH.MESH.02233126-187 - Prolift+M Educational Module ETH.MESH.02233290 ETH.MESH.02233410-416 - Prosima US Launch Pre-Market Preparation (Sept. 2009) ETH.MESH.02233417 - Prosima New Product Request Form ETH.MESH.02233418-438 - Prosima - Surgical Technique ETH.MESH.02233439-451 - A New Operation for Vaginal Prolapse Reapir Using Mesh and a Vaginal support Device: 1 Year Anatomic and Functional Results of an International, Multicenter Study. ETH.MESH.02233452-467 - Prosima - Background and Development History ETH.MESH.02233468-538 - Prosima Prof Ed (71 slides) ETH.MESH.02233539 - Prosima - New Product Request Form ETH.MESH.02233540-625 - Prosima - 2009 Sales Training Program ETH.MESH.02233605 - (B&W) Webinar Invite "The treatment of Symptomstiv Moderate Pelvic Organ Prolapse." ETH.MESH.02233640 - (B&W) Prosima - Module 4: 2-Year Clinical Data ETH.MESH.02233651-673 - One year Clinical Outcomes Following Prolapse Surgery with Non-Anchored Mesh and a Vaginal Support Device. Results from the International Multicenter Gynecare Prosima ™ Study. ETH.MESH.02233674-692 - (Marketing) "What is Gynecare Prosima Pelvic Floor Repair System?" ETH.MESH.02233699-710 - Prosima - An Interview with Dr. Marcus P. Carey. ETH.MESH.02233713-714 - Objective Success Rate Learning Guide

ETH.MESH.02233726-727 - Prosima Product Page on Ethicon-360 ETH.MESH.02233728 - Gynecare Prosima ™ Key Procedural Steps

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#### **Production Materials**

ETH.MESH.02233751-833 - Prosima Prof Ed 2 (83 slides)

ETH.MESH.02233834 - (B&W) 2009 Sales Aid Guide

ETH.MESH.02233840-841 - MRI Flashcard "Prosima - The first fixationless mesh system that maintains anatomical position."

ETH.MESH.02233842 - Virtual Round Table Registration Form

ETH.MESH.02233843-849 - Clinical Study Findings Discussion for Gynecare Prosima ™ by Piet Hinoul (Audio Transcript).

ETH.MESH.02233851 - Document entitled "PROS-438-10-9/12 Prosima Short Procedural Video."

ETH.MESH.02233857-859 - AJOG Press Release (Draft)

ETH.MESH.02233857-859 - Prosima 1 year study letter

ETH.MESH.02233862-880 - AALG in booth presentation. "Proof in the Treatment of Pelvic Organ Prolapse" Douglas Van Drie, M.D.

ETH.MESH.02233881-888 - Zyczynski, H.M. "One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device." Am J Obstet Gynecol (2010) 203.

ETH.MESH.02233956 - Prosima Updates to Ethicon360

ETH.MESH.02233961 - Virtual Round Table Follow-up Letter.

ETH.MESH.02233962 - Virtual Round Table Follow-up Letter.

ETH.MESH.02233963 - Virtual Round Table Invitation

ETH.MESH.02233964 - (B&W) Prosima DVD

ETH.MESH.02234001-002 - (Marketing) The Gynecare Prosima ™ Pelvic Floor Repair System Story

ETH.MESH.02234005-171 - Prosima Sales Training Program

ETH.MESH.02234173-177 - Prosima Messgaging practice Coaching Check List

ETH.MESH.02234195-196 - Prosima Workshop Takeaway

ETH.MESH.02235456-473

ETH.MESH.02235474-502

ETH.MESH.02237107-115 - Introducing Gynecare Prosima for Ethicon Epiphany 247.

ETH.MESH.02237107-115 - Prosima Kevin Frost Presentation (moderate to severe)

ETH.MESH.02248778 - Mechanical vs Machine Cut (Laser.Ultrasonic) Mesh Particle loss less than 2 percent for both (January 19, 2005)

ETH.MESH.02248848 - Gynecare TVT Secur Powerpoint (Engleman/Adkins Trial Exhibit P0842)

ETH.MESH.02259836 - Graft or no graft finl 11-21-04

ETH.MESH.02270724 - (07.19.2003) Email string, top one from Michel Cosson to Scott Ciarrocca re: Gynemesh holding force in tissue.

ETH.MESH.02270766-767 - (11.21.2003) Email string, top one from Michel Cosson to Scott Ciarrocca re: D'Art, risk question.

ETH.MESH.02270857-858 - (07.16.2004) Email from Laura Angelini to multiple recipients re: D'Art - Conversation with Prof. Jacquetin.

ETH.MESH.02286052-053 - Email string, top one from S. O'Bryan to S. Ciarrocca re: Prolift IFU

ETH.MESH.02293981 - Email from Adrian Roji dated 7/19/11 re Approved FDA Notification Respo

ETH.MESH.02318553-554 - Gynecare Prosima ™ Combined Pelvic Floor Repair System Clinical Strategy.

ETH.MESH.02319312 - Memo re-TVT-base & TVT-O Complaint Review for Laser Cut Mesh Risk Analysis

ETH.MESH.02319408-409 - Email from David Robinson to Cyrus Guidry dated 4.17.07 enclosing powerpoint "Factors Related to Mesh Shrinkage - What do we know? A review of literature and internal studies" (Engleman/Adkins Trial Exhibit P0863)

**Production Materials** ETH.MESH.02322037-039 - Email string, top one from Piet Hinoul to Aaron Kirkemo, et al. re: Neo clinical trial. ETH.MESH.02330766 ETH.MESH.02330767 - Marketing Materials for Prosima ETH.MESH.02330776 - TVT-O (TVTO-384-10-8.12) ETH.MESH.02340331-335 - TVT IFU (12.22.03 to 02.11.05) ETH.MESH.02340471-503 ETH.MESH.02340568-590 - TVT-Secur Instructions for Use (12/16/2005 to Discontinuance) (Engleman/Adkins Trial Exhibit P0871) ETH.MESH.02340568-755 ETH.MESH.02340829-835 - TVT-O IFU - (01.07.04 to 03.04.05) ETH.MESH.02341203-213 - TVT Abbrevo IFU ETH.MESH.02341203-266 - TVT Abbrevo IFU ETH.MESH.02341398-410 - Prosima IFU (6.18.10 to discontinuance) - English only 13 pages ETH.MESH.02341398-453 - Prosima IFU 2008 P21070 D ETH.MESH.02341454-459 - Gynecare Prolift IFU (English Only) ETH.MESH.02341454-521 ETH.MESH.02341522-527 - 2005 Gynecare Prolift IFU (English Only) ETH.MESH.02341522-589 ETH.MESH.02341658-664 - Gynecare Prolift IFU (English Only) ETH.MESH.02341658-733 ETH.MESH.02341734-740 - Prolift 2009-2010 IFU ETH.MESH.02341734-809 ETH.MESH.02342097 - Prolene Soft IFU (4.13.09 - 8.22.10) ETH.MESH.02342101 - Prolene Soft IFU ETH.MESH.02342102 - Prolene Mesh IFU ETH.MESH.02342152-154 - Prolene Mesh IFU ETH.MESH.02342194-196 - Gynecare Gynemesh PS IFU (English Only) 03.20.03 - 03.30.06 ETH.MESH.02342218-220 - Gynecare Gynemesh PS IFU (English Only) ETH.MESH.02342250-252 - Gynecare Gynemesh PS IFU (English Only) ETH.MESH.02342278-279 - Gynecare Gynemesh PS IFU (English Only) ETH.MESH.02596085 - Letters to the Editor 2010; 1457 ETH.MESH.02597949-950 - Hinoul P, et al. "A "mesh" made in heaven: synergy between the urogynaecological device industry and evidence based medicine." ETH.MESH.02599918-920 - Email string, top one from Piet Hinoul to Kevin Frost re: 1-year Prosima Data Conference Call. ETH.MESH.02603812-821 - Dissection Techniques in Transvaginal Pelvic Organ Prolapse Repair with Synthetic Mesh ETH.MESH.02614610-624 ETH.MESH.02615519-658 ETH.MESH.02616825-827 - Prolene Soft IFU ETH.MESH.02656825-834 - Issue Report TVT-O 2010 ETH.MESH.02658316 - Cover Letter ETH.MESH.02910418-421 - Axel Arnaud Email to Martin Weisberg et al dated 11.26.2002 re mini TVT mesh

adjustment (Engleman/Adkins Trial Exhibit P0933) ETH.MESH.02916532-615 - Clinical Study Report - Evaluation of the TVT Secur System for Stress Urinary

Incontinence (Engleman/Adkins Trial Exhibit P0934)

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### **Production Materials**

ETH.MESH.02967410-412 - Study: Prosima (300-06-005); Plots/charts for 12-month vs. baseline safety analysis set.

ETH.MESH.03048942 - Document entitled "New" Mint January 05, 2006.

ETH.MESH.03049774-775 - Gynecare Prosima\* Combined Pelvic Floor Repair System: Clinical Strategy.

ETH.MESH.03056578-580 - Email string from Colin Urquhart to David Robinson and Judith Gauld re: Prosima\* investigator bulletin.

ETH.MESH.03086214-219 (Adkins Trial Exhibit P0946)

ETH.MESH.03109341 - Email string, top one from Judi Gauld to Halina Zyczynski re: Prosima well received at AUA.

ETH.MESH.03160821 - Email from Judith Gauld to Allison London Brown re: US Prosima Sites; cc: David Robinson, et al.

ETH.MESH.03160822-823 - Email string, top one from Judith Gauld to Stephanie Kute re: MINT Design Validation Dates; cc: Dan Smith, et al.

ETH.MESH.03160827-828 - Email string, top one from Colin Urquhart to Stephanie Kute re: Doctors contacted for DVal as of today; cc: Judith Gauld, et al.

ETH.MESH.03162936-938 - Email string from Judith Gauld to David Robinson and Jonathan Meek re: Marcus Carey US visit.

ETH.MESH.03172197-198 - Internal email from Harel Gadot to David Robinson dated 06.20.2006 re proposed RCT (Engleman/Adkins Trial Exhibit P0953)

ETH.MESH.03259439-440 - 4.24.2009 Gauld email chain re Green Journal

ETH.MESH.03361293 - Mesh Platform Review: Somerville, November, 2010.

ETH.MESH.03361673-689 - 2003 TVT-O Report - Cadaver lab - IFU Device Adequate by Outside surgeon

ETH.MESH.03378923-933 - Prosima Patient Brochure - Stop Coping Start Living

ETH.MESH.03393725-731 - Sikirica, V, et al. "Sexual Function 12 Months Following Vaginal Prolapse Repair Augmented by Mesh and a Vaginal Support Device" ICS/IUGA (2010) Abstract

ETH.MESH.03396246 - VSD Patient Information (Slim Jim) - "Stop Coping Start Living."

ETH.MESH.03427757-759 - EWHU eClinical Compendium - Article Summary. Barber, M.D., et al. "Transobturator Tape Compared with Tension-free Vaginal Tape for the Treatment of Stress Urinary Incontinence: A Randomized Controlled Trial.

ETH.MESH.03427878-883 - TVT IFU - (11.29.10 to11.26.14)

ETH.MESH.03427878-945

ETH.MESH.03439842-846 - Prosima Sales Aid Training Deck - "What could a truly tension-free repair mean for you and your patients?"

ETH.MESH.03440816-836 - Prosima Revised Webinar Deck - Overview

ETH.MESH.03458123-138

ETH.MESH.03459088-104

ETH.MESH.03460813-853 - Prolift Surgeon's Resource Monograph, approved 4.13.2007

ETH.MESH.03460813-884 - Prolift Surgeons Resource Monograph

ETH.MESH.03466382-383 - DX24665 - Bedestani email re Prosima

ETH.MESH.03471308 - Chart entitled "Pedm Monthly Status."

ETH.MESH.03497846-847 - MDD Complaint Form Complaint ID CC1007005

ETH.MESH.03612364 - Gynecare Prosima Pelvic Floor Repair Preceptorship, Course Overview.

ETH.MESH.03620412-413

ETH.MESH.03620414

ETH.MESH.03620415

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### **Production Materials**

ETH.MESH.03626267-269 - Email string, top one from Jennifer Paradise to Susie Chilcoat re: Prosima Professional Education Slide Deck Conference Call.

ETH.MESH.03643186 - Ethicon Women's Health and Urology Brand Equity Study Final Report Powerpoint (Engleman/Adkins Trial Exhibit P1008)

ETH.MESH.03643392-395 - Email string, top one from Jennifer Paradise to Adrian Roji, et al. re: Approved for distribution: FDA Notification FAQS and Customer Letter.

ETH.MESH.03667696-704 - Company Procedure for US Regulatory Affairs Review of Promotion and Advertising Materials for Medical Devices.

ETH.MESH.0370392 - 2007 TVT-Secur (3914\_2007-08-22)

ETH.MESH.03715787-793 - Gynemesh PS CER (2002) - Weisberg

ETH.MESH.03715978 - Weisberg email re: TVT question.

ETH.MESH.03725540-553 - Memo dated 07.06.2010 re EWHU innovation counsel (Engleman Trial Exhibit P2572)

ETH.MESH.03736120-127 - Gynemesh PS: A New Mesh for Pelvic Floor Repair Early Clinical Experience

ETH.MESH.03751819

ETH.MESH.03845446-450 - Darryl Harkness email to Aran Maree dated 10.30.2007 re secur update presented in at WW marketing meeting (Engleman Trial Exhibit P1063)

ETH.MESH.03895925-927 - DX24789 - Bedestani email re Prosima

ETH.MESH.03904968-975

ETH.MESH.03905472-477 - Email string re-TVT recommendation from Dr. Alex Wang

ETH.MESH.03905968-975 - 2005 Prolift Patient Brochure: POP, Get the facts, be informed, make your best decision

ETH.MESH.03905976-991 - Prolift Patient Brochure: POP, Get the facts, be informed, make your best decision

ETH.MESH.03905992-6000

ETH.MESH.03906001-6020 - Prosima and Prolift+M Patient Brochure: What You Should Know About Pelvic Organ Prolapse. Stop Coping. Start Living. Dated 11/9/2009

ETH.MESH.03906037-052 - Prolift Patient Brochure: Treatment Options for POP, stop coping, start living

ETH.MESH.03907468-469 - Second Generation TVT - by Axel Arnaud

ETH.MESH.03910175-177 - Email string re - Soft Prolene (Adkins Trial Exhibit P1080)

ETH.MESH.03910418-421 - Email string re-Mini TVT - mesh adjustment

ETH.MESH.03911107-108 - Email string re-TVT complications (an Prof. Hausler)

ETH.MESH.03911901-910 - Deprest J, et al. The biology behind fascial defects and the use of implants in pelvic organ prolapse repair. Int Urogynecol J (2006)

ETH.MESH.03913357-359 - Axel Arnaud Email 5.31.07 Re TVT TVT-O

ETH.MESH.03916905-913 - Plaintiff's Exhibit 3827

ETH.MESH.03917375-378 - (11.26.2002) Email string, top one from Martin Weisberg to Dr. Richard Juraschek, et al. re: Mini TVT - mesh adjustment.

ETH.MESH.03921355-156 - Miller, D. Prospective Clinical Assessment of the Total Vaginal Mesh (TVM)

Technique for Treatment of Pelvic Organ Prolapse - 6 and 12 month results.

ETH.MESH.03921612 - E-mail from Ralf Gotter to Arnaud and Gadot dated 11.30.2006 regarding, "The more procedures the more problems." (Engleman/Adkins Trial Exhibit P1096)

ETH.MESH.03922953 (Adkins Trial Exhibit P1100)

ETH.MESH.03923121-122 - Andrew Beveridge email to Julie Hocknell and Axel Arnaud dated 02.20.2008 re trip to Israel (TVT-S complication summary) (Engleman/Adkins Trial Exhibit P1102)

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### **Production Materials**

ETH.MESH.03924557-586 - Meshes in Pelvic Floor Repair-Findings from literature review and conversations-interviews with surgeons, June 6, 2000.

ETH.MESH.03930120-123 - Nilsson C. Seven-Year Follow-up of the Tension-Free Vaginal Tape Procedure for Treatment of Urinary Incontinence. Obstet Gynecol 2004; 104(6): 1259-62

ETH.MESH.03932909-911 - Confidential 2007 History of TVT-O by Axel Arnaud

ETH.MESH.03932912-914 - 2000 The history of TVT by A. Arnaud (7.12.2000)

ETH.MESH.03941623 - DeLeval Email RE: TVT ABBREVO ALERT - French and English Email and English Translation Certification Plaintiff's Exhibit 3619- Perry

ETH.MESH.03958008

ETH.MESH.03959337 - Prolift+M vs. Prosima - 2 year results

ETH.MESH.03962244 - Dear Surgeon letter 7/18/11

ETH.MESH.03984409-410 - Email string, top one from Scott Finley to Greg Prine re: Pelvic Floor Repair Customer Meeting.

ETH.MESH.03989722-723 - Email string, top one from Jim Gatewood to Rebecca Ryder re: Prosima 2 Year data Dinner.

ETH.MESH.03989781-782 - Email from Jim Gatewood to Marilyn Valdes re: Norfolk, VA, Dec 2, 2010 Prosima Awareness Dinner Information.

ETH.MESH.03991591-592 - Memo re: Gynecare Studies; created by Randall Gore.

ETH.MESH.04005090-091 - Ethicon informs FDA of discontinuation

ETH.MESH.04005092-093 - Ethicon's Notification to FDA to Decommercialize

ETH.MESH.04005095-096 - Ethicon's Notification to FDA regarding Decommercialization

ETH.MESH.04042511-512 - Slack, M., et al. Presentation Title: "Clinical Experience of a Novel Vaginal Support Device and Balloon used to Simplify Mesh Augmented Vaginal surgery for Prolapse."

ETH.MESH.04046302 - Powerpoint: TVT and TVT-O Update

ETH.MESH.04048515-520 - KOL Interview with Carl Nilsson re intent for next generation mini sling, intent for 2 distinct devices O and R and breakdown of current TVT-S usage in US (Engleman/Adkins Trial Exhibit P1128)

ETH.MESH.04077172 - Powerpoint: Gynecare LatAm Moments at IUGA Congress 2010

ETH.MESH.04079609

ETH.MESH.04081189 - Meeting Agenda

ETH.MESH.04082973 - Possible Complications for Surgeries to Correct POP and SUI

ETH.MESH.04092868 - Email re: 10100080654 and TVT IFUs

ETH.MESH.04093125 - Meng Chen email to Bryan Lisa dated 11.30.2006 re TVT IFUs on tape extrusion, exposure and erosion (Engleman/Adkins Trial Exhibit P1139)

ETH.MESH.04181761-762 - Gynecare Prolift Pelvic Floor Repair

ETH.MESH.04201880 - Prosima Training Deck 2

ETH.MESH.04202101 (2008-448)

ETH.MESH.04206959

ETH.MESH.04381806-819 - Literature Review on Biocompatibility of Prolene Sutures and Impants

ETH.MESH.04385229-245 (Adkins Trial Exhibit P1177)

ETH.MESH.04427456-457 - FDA Letter re: K063562 Gynecare Prosima Pelvic Floor Repair Systems

ETH.MESH.04465690 - MSE0079 - Material Specification for Gynemesh PS - Revision A

ETH.MESH.04474731 - Ethicon's Cover Letter Response to TVT Secur 522 Order

ETH.MESH.04474756-760 - Hota, et al. (2012) TVT Secur (Hammock) versus TVT Obturator: a randomized trial of suburethral sling operative procedures. Female Pelvic Med Reconstr Surg; 18(1), January/February 2012 (Engleman/Adkins Trial Exhibit P1185)

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### **Production Materials**

ETH.MESH.04476265-272 - April 24 2012 email to FDA

ETH.MESH.04499687-742 - (Adkins Trial Exhibit P0036)

ETH.MESH.04543335 - Pelvic Organ Prolapse Surgical Mesh Discussion call in information 9/12/11

ETH.MESH.04543336 - Pelvic Organ Prolapse Surgical Mesh Discussion call in information 9/12/11

ETH.MESH.04548931-935

ETH.MESH.04550996-997 - Email string, top one from Piet Hinoul to Marcus Carey and Richard Gooding re: Prosima VSD.

ETH.MESH.04551757-795 - Email with attachment from Piet Hinoul to Jeffrey Hammond, Dr. James Hart, et al. regarding Benefit risk profile TVM

ETH.MESH.04551946 - Ethicon Gynecare WW Commercialization Decision - US Surgeon Letter 6/1/12

ETH.MESH.04554662 - Ethicon Gynecare WW Commercialization Decision - US Frequently Asked Questions 6/1/12

ETH.MESH.04554687 - FDA letter to Ethicon re 522 Orders (Kanerviko 2013-08-22 29)

ETH.MESH.04558399-409 - Iglesia C. Vaginal Mesh for Prolapse: A Randomized Controlled Trial. Obstet Gynecol 2010:116:293-303

ETH.MESH.04567040-044 - FDA's Response to proposed study plan-04.02.2012

ETH.MESH.04567080 - FDA's Resposne to Discontinuation and Agreement to Hold 522 Responses

ETH.MESH.04567174 - US Discussion Guide for Use with Customers 5/15/12

ETH.MESH.04567674 - Core Messages 5/15/12

ETH.MESH.04567677 - Frequently asked questions 5/15/12

ETH.MESH.04567680 - Message from Laura Angelini to Internal WW Associates 5/15/12

ETH.MESH.04567686 - US Sales Call Script for Matt Henderson 5/15/12

ETH.MESH.04567695 - Ethicon Gynecare WW Commercialization Decision - Core Messages 6/1/12

ETH.MESH.04567698 - Ethicon Gynecare WW Commercialization Decision - Standby Statement 6/1/12

ETH.MESH.04567707 - Ethicon Gynecare WW Commercialization Decision - Chuck Austin Message to WW General Surgery Employees 6/1/12

ETH.MESH.04567726 - Ethicon Gynecare WW Commercialization Decision - Tim Schmid message to US General Surgery Employees 6/1/12

ETH.MESH.04568519 - Email from Matt Henderson to Tim Schmid re: 522 Communication Recap.

ETH.MESH.04568717-719 - DX24785 - Khandwala email re Prolift+M

ETH.MESH.04925426 - DX10341 Beath email to Kanerviko

ETH.MESH.04926150-151 - DX24802 - Piet discussing 522 order

ETH.MESH.04926191-192

ETH.MESH.04927339-340 - FDA's Resposne to Discontinuation Notification-07.09.2012

ETH.MESH.04931596 - Kanerviko email re 40000 page response to 522

ETH.MESH.04938298-299 - Piet Hinoul Email Re: Prof. de Leval - TVT Abbrevo

ETH.MESH.04939001

ETH.MESH.04941016 - (P041122) Lightweight Mesh Development presentation

ETH.MESH.04945231-239 - Email string re-Ultrapro vs Prolene Soft Mesh

ETH.MESH.04945496 - Bernd Klosterhalfen Email Re: Ultrapro vs. Prolene Soft Mesh April 18, 2005

ETH.MESH.04984220-221 - DX24790 - Lucente email

ETH.MESH.05009194

ETH.MESH.05092843-843 - Chart listing lab schedule for August 11th.

ETH.MESH.05106233-234 - Email string, top one from Kevin Frost to danhalt@gmail.com, et al. re: Reminder:

Prosima Professional Education Slide Deck Conference Call Tonight 7pm EST.

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### **Production Materials**

ETH.MESH.05164225-226 - EWHU eClinical Compendium - Article Summary. Reisenauer, C., et al. "Anatomic study of prolapse surgery with nonanchored mesg and a vaginal support device."

ETH.MESH.05165675-677 - EWHU eClinical Compendium - Article Summary. Barber, M.D., et al. "Defining success after surgery for pelvic organ prolapse." Obstet Gynecol (2009) 114:600-609.

ETH.MESH.05217098-100 - FDA Clearance Letter, Modified PROLENE

ETH.MESH.05217103-144 - Letter to FDA re: Notification of Intent

ETH.MESH.05222673-705

ETH.MESH.05222686-688 - TVT IFU (4th version) 4.7.06-10.7.08

ETH.MESH.052235354-385

ETH.MESH.05225380-384 - TVT IFU - (09.08.00 to 11.26.03)

ETH.MESH.05234758-762 - Dr. Kerstein Spychaj memo dated 12.12.2006 re State of the knowledge in "mesh shrinkage" - what do we know? (Engleman/Adkins Trial Exhibit P1235)

ETH.MESH.05320909 - 2008 Treatment of Stress Urinary Incontinence with Gynecare TVT Secur System

ETH.MESH.05321899

ETH.MESH.05321900

ETH.MESH.05337217-220 - Email string, top one from D. Miller to J. Paradise, et al

ETH.MESH.05343480-482 - Email string, top one from Joseph Lanza to Bart Pattyson re: Review EWHU IUGA events.

ETH.MESH.05343757-758 - Email string, top one from Kevin Frost to Bart Pattyson re: July 31 Heads Up; cc: Lissette Caro-Rosado.

ETH.MESH.05347751-762 - Email string re Investigator-initiated studied policy

ETH.MESH.05439518-522 - Sunoco MSDS

ETH.MESH.05446127-139 - Joerg Holste email to Dr. Dieter Engel et al dated 03.13.2006re mesh and tissue contraction in animal (Engleman/Adkins Trial Exhibit P1846)

ETH.MESH.05469908-912 - Email string, top one from Thomas Barbolt to Dr. Joerg Holste, et al. re: Ultrapro; cc: Laura Angelini, et al.

ETH.MESH.05475773-822 - Borist Batke powerpoint - The (clinical) argument of lightweight mesh in abdominal surgery (Engleman/Adkins Trial Exhibit P1274)

ETH.MESH.05479411 - The (clinical) argument of lightweight mesh in abdominal surgery

ETH.MESH.05479535 - Mesh porosity chart (Engleman Trial Exhibit P1278)

ETH.MESH.05559108-109 (Adkins Trial Exhibit P1318)

ETH.MESH.05571741 - Email string, top one from Jim Gatewood to Robert Zipfel re: Gynecare Prof Ed -

Approved: Request for Speaker Event.

ETH.MESH.05573916-917 - Email string, top one from Kevin Frost to Jennifer Paradise re: Prosima VRT Reminder - Honoraria Payments; cc: Paul Parisi.

ETH.MESH.05588123-126 - Stephen Wohlert Email - AW: How inert is polypropylene? July 9, 2007

ETH.MESH.05600916-923 - Background Information Gynecare Pelvic Floor Repair Products and Gynecare TVT Secur (Engleman Trial Exhibit P1327)

ETH.MESH.05644163-171 - Pelvic Floor Repair-Surgeon's Feed-back on Mesh Concept

ETH.MESH.05741094 - Email from Rhonda Peebles to Samuel Sheelu, et al. re: Additional room for Ask the Expert sessions; cc: Alyson Wess, et al.

ETH.MESH.05741890-891 - Email string, top one from Christopher Teasdale to Tom Affeld, et al. re: Additional room for Ask the Experts sessions.

ETH.MESH.05779953-957

ETH.MESH.05795097-104 (Adkins Trial Exhibit P1352)

ETH.MESH.05795421-508

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### **Production Materials**

ETH.MESH.05795509-536

ETH.MESH.05795537-599

ETH.MESH.05795600-621

ETH.MESH.05799233-239 - TVT Exact IFU

ETH.MESH.05820723 - Dear Surgeon Letter re Discontinuation

ETH.MESH.05835298-308 - Pelvic Organ Prolapse - Patient Counseling Guide.

ETH.MESH.05837063-110 - Pelvic Organ Prolapse Value Dossier. Gynecare Prolift, Gynecare Prolift +M, Gynecare Prosima.

ETH.MESH.05837242 - DX23938 - Letter re FDA 2011 Notice

ETH.MESH.05840629 - Powerpoint Presentation entitled "Continuum of Education."

ETH.MESH.05918776 - Email re: Marlex Experience

ETH.MESH.05922038 - Letter from Patricia Nevar to Jaime Sepulveda, M.D. re: Secrecy Agreement for Prosima.

ETH.MESH.05947160-163 - Email from Patricia Holland to Andre Fontes re: Partnership Plus Follow up Gynecare Reminder; cc: Fernando Nassif, et al.

ETH.MESH.05958248 - Surgeons Resource Monograph

ETH.MESH.05958527-530

ETH.MESH.05960623

ETH.MESH.05967586-587 - Email string, top one from Robert Zipfel to Susie Chilcoat re: Prosima Preceptor-Led Virtual Round Tables (VRTs) faculty payment.

ETH.MESH.05998835-836 - Piet Hinoul Email Re: ALERTE TVT ABBREVO

ETH.MESH.06087210-212

ETH.MESH.06087471-472

ETH.MESH.06087513-514

ETH.MESH.06090245

ETH.MESH.06113091-092 - Email from Debra Mayfield to DL-ETHUSSO EWHU WESTERN REGION re: Prosima VRT Invitation Plan - due Jan 28.

ETH.MESH.06124656-657 - Email string, top one from Andrew Meek to Bart Pattyson re: Prosima training.

ETH.MESH.06124954-955 - Email string, top one from Bart Pattyson to Marcos Fujihara re: Prosima training in Miami with Dr. Jaime Sepulveda.

ETH.MESH.06125000-001 - Email string, top one from Bart Pattyson to Robert Zipfel re: Prosima in LATAM.

ETH.MESH.06125058 - Email from Bart Pattyson to Eugene Brohee re: June 21 - Latin America doctors in town; cc: Selena Lessa.

ETH.MESH.06125098 - Email string, top one from Bart Pattyson to Georgia Long re: updated agenda - May 8th.

ETH.MESH.06125277 - Email string, top one from Marcos Fujihara to Bart Pattyson, et al. re: Prosima presentation in Miami.

ETH.MESH.06125309 - Email string, top one from Robert Zipfel to Bart Pattyson re: Prosima in LATAM.

ETH.MESH.06125502 - Email string, top one from Georgia Long to Bart Pattyson re: may 8th.

ETH.MESH.06151466-467 - Email string, top one from David Robinson to Judith Gauld re: Jaime Sepulveda.

ETH.MESH.06151983-984 - David Robinson email to Allison London Brown dated 08.26.2006 re TVT-S results to week 5 (31 patients) (Engleman/Adkins Trial Exhibit P1403)

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### **Production Materials**

ETH.MESH.06238611 - Email from Mark Kenyon to Aaron Kirkemo re: NEO Surgical Guide - Role & Responsibilities; cc: Vincenza Zaddem.

 ${\sf ETH.MESH.06255523-534-Gynecare\ Prosima\ ^{\sf m}\ Pelvic\ Floor\ Repair\ System.\ ''An\ Expert\ Interview\ with\ Dr.}$ 

Marcus P. Carey, MBBS, FRANZCOG, CU, the Inventor of the Gynecare Prosima System."

ETH.MESH.06382976-987 - Jia, X. Efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse: systematic review and meta-analysis. BJOG 2008; 115: 1350-1361

ETH.MESH.06388151 - Powerpoint: Prolift Pelvic Floor Repair - MDV Reported Complaints

ETH.MESH.06400722 - GYNECARE GYNEMESH PS CE Mark Technical File

ETH.MESH.06480608-609 - Email string, top one from Judith Gauld to Stephanie Kute re: MINT Design Validation Dates; cc: Dan Smith, et al.

ETH.MESH.06482821-822 - Email from Judith Gauld to Tony Smith re: Prosima Investigator Meeting; cc: David Robinson.

ETH.MESH.06585815 - Powerpoint: Agenda

ETH.MESH.06591558-559 - Email string, top one from Tom Affeld to Shwetal Narvekar re: Pre-launch Awareness for Prosima with Dr. Marcus Carey; cc: Bart Pattyson, et al.

ETH.MESH.06592243 - 09.14.2012 Email from Carl Nilsson to Laura Angelini

ETH.MESH.06695438 - Justification for Utilizing the Elasticity Test as the Elongation Requirements on TVT LCM

ETH.MESH.06696367-379 - Performance Evaluation of TVT U Prolene Mesh

ETH.MESH.06769156 - Powerpoint: A New Operation for Vaginal Prolapse Repair Using Mesh and a Vaginal Support Device: 1 Year Anatomic and Functional Results of an International, Multicenter Study. Mark Slack, Cambridge, UK for the Prosima Study Group.

ETH.MESH.06861281 - Scott Ciarrocca email to David Robinson and Dan Smith dated 01.21.2008 re TVT Secur Data (Engleman Trial Exhibit P1437)

ETH.MESH.06887138-140 - Waltregny email written on behalf of Professor de Leval.

ETH.MESH.06887244 - 07.16.04 David Waltregny email to Dan Smith re: TVT-O.

ETH.MESH.06893564-565 - Email from Folke Flam to Aviram Suchard dated 09.25.2006 re feedback after using TVT Secur after the launch (Engleman/Adkins Trial Exhibit P1452)

ETH.MESH.06894461-467 - Klinge 2002 Impact of polymer pore size on the interface scar formation in a rat model (Engleman Trial Exhibit P1454)

ETH.MESH.06917699-704 - Form For Customer Requirements Specification (CRS) For Project TVT-O PA

ETH.MESH.06923868-871 - TVTO-PA Clinical Strategy - 8.21.13 Exhibit A.M. Mitchell T-2177

ETH.MESH.06927248-249 - Dan Smith email to Paul DeCosta et al dated 03.19.2010 re Scion Evaluation Comparison file (EnglemanAdkins Trial Exhibit P1460)

ETH.MESH.07090179-181 (Adkins Trial Exhibit P1463)

ETH.MESH.07105727 - Email string, top one from Laura Vellucci to Colin Urguhart re: Prosima publication.

ETH.MESH.07181042-043 (Adkins Trial Exhibit P1464)

ETH.MESH.07186593-624 (Adkins Trial Exhibit P1467)

ETH.MESH.07189091 - Powerpoint: From presentation to publication: ensuring quality in the reporting of urogynaecology research. IUGA "This house believes that industry sponsorship has a corrosive influence on standards of scientific reporting." Conflict of interests: Piet Hinoul, M.D.

ETH.MESH.07190144-145 - Email string, top one from Judi Gauld to Piet Hinoul, Colin Urquhart re: +M Abstract.

ETH.MESH.07192929 - Investigating Mesh Erosion in Pelvic Floor Repair Powerpoint

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### **Production Materials**

ETH.MESH.07201006 - Prolift Professional Education Slide Deck (2007)

ETH.MESH.07219196-209 - Clinical Expert Report - Prosima ™ signed by David Robinson.

ETH.MESH.07226579-590 - 2000 TVT CER

ETH.MESH.07229215-245 - Clinical Expert Report - Prosima ™ signed by Piet Hinoul.

ETH.MESH.07246690-719

ETH.MESH.07296496 - Chart listing Week Schedule and Lab Flow.

ETH.MESH.07308636-637 - Email from Tom Affeld to Clifford Volpe, et al. re: Surgeon's view on Prosima; cc:

Lissette Caro-Rosado, et al.

ETH.MESH.07324554-555

ETH.MESH.07351297

ETH.MESH.07374762-763 - Email from Lissette Caro-Rosado to Jaime Sepulveda, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattyson, et al.

ETH.MESH.07379573-574 - Email string, top one from Kevin Frost to Ahmet Bedestani, et al. re: Purpose; cc: Matt Henderson, et al.

ETH.MESH.07383398 - FW Information Regarding FDA Notification of Use of Mesh in Pelvic Surgery

ETH.MESH.07383730-731 - Email string re-Ultrapro mesh information-identical mesh to Prolift +M

ETH.MESH.07384790-791 - Email string, top one from Robert Zipfel to Lissette Caro-Rosado re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones, and Schlafstein on Monday Jan 4, 2010.

ETH.MESH.07452663 - Power Point - Neuchatel Particles in TVT-O Blisters

ETH.MESH.07462313 - Email from Adrian Roji dated 8/19/11 re update message to the field re FDA notification response

ETH.MESH.07587090-091 - Email string, top one from Judith Gauld to Patricia Nevar re: Dr. Sepulveda; cc: Colin Urquhart.

ETH.MESH.07628243 - EWH&U Gynecare Prosima ™ Pelvic Floor Repair System Faculty Checklist.

ETH.MESH.07630654 - Email string, top one from Greg Prine to Stevan Barendse, Robert Zipfel re: Prosima targets.

ETH.MESH.07631488 - Email string, top one from Selena Lessa to Robert Zipfel re: Prosima course with Sepulveda.

ETH.MESH.07631752-753 - Email string, top one from Eric Globerman to Nicole Huffman re: Prosima course; cc: Robert Zipfel.

ETH.MESH.07631967-968 - Email string, top one from Stacy Hoffman to Robert Zipfel, Kimberly Heath re: Prosima Lab.

ETH.MESH.07632042 - Event request form for Sepulveda Preceptorship.

ETH.MESH.07632042-043 - Email from Kevin Frost to danhalt@gmail.com, et al. re: Save the Date: Prosima Faculty Conference Call 7/20 at 7pm EST; cc: Jennifer Paradise.

ETH.MESH.07636090 - Prosima Cadaver Lab Invitation

ETH.MESH.07653362-363 - Email string, top one from Tommaso Santini to Kevin Frost, et al. re: US Surgeon; cc: Tom Affeld.

ETH.MESH.07898852-871 - Linda Nichols email to Linda Answell et al dated 12.01.2004 re TVTx Charter document for 12/06 GAT meeting (Engleman/Adkins Trial Exhibit P1527)

ETH.MESH.07903682-683

ETH.MESH.07931680-681 - Email string, top one from Bart Pattyson to Jeff Hsieh re: Prosima Professional Education Slide Deck Conference Call.

ETH.MESH.07951163 - Document re: Prosima's apical/anatomical success rates and functional outcomes.

ETH.MESH.07953429-433 - EWH&U 2011 Field Visit Letter

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### **Production Materials**

ETH.MESH.07977911
ETH.MESH.08003173-180
ETH.MESH.08003181-196

ETH.MESH.08003215-230 - Ethicon Copy Review Submission form: GYNECARE TVT Tension-free Support for Incontinence Patient Brochure. Submitted by Robin Osman dated 07.12.2006 (Engleman Trial Exhibit P1536)

ETH.MESH.08003231-246

ETH.MESH.08003197-212

ETH.MESH.08003247-262

ETH.MESH.08003263-278 - Ethicon Copy Review Submission form: GYNECARE TVT Tension-free Support for Incontinence Patient Brochure (Including TVT Secur) dated 05.29.2009 (Engleman Trial Exhibit P1539)

ETH.MESH.08003279-294

ETH.MESH.08003295-302

ETH.MESH.08003303-318

ETH.MESH.08021804-807 - Email string, top one from Libby Lewis to Kenneth Pagel, et al. re: Journal Club - trocar-less vaginal mesh kits.

ETH.MESH.08023741-744 - Email string, top one from Scott Miller to Jonathan Fernandez re: Prosima Take Away Messages.

ETH.MESH.08033153 - Document entitled "Prevalence and risk factors for mesh erosion after laparoscopic-assisted sacrocolpopexy." Author(s) Jasmine Tan-Kim, Shawn A, Menefree, Karl M, Luber, Charles W. Nager, Emily S. Lukacz.

ETH.MESH.08041930-931 - Michelle Irvin email RE 12.08.2010 post call notes (Engleman Trial Exhibit P2563)

ETH.MESH.08048738-740 - Email from David Jackson to Selena Lessa re: Prosima course with Sepulveda.

ETH.MESH.08066452

ETH.MESH.08107354

ETH.MESH.08117473

ETH.MESH.08117625-626

ETH.MESH.08135444 - Gynecare Prosima - Pelvic Floor Repair System Proctorship

ETH.MESH.08139049-118 - Pelvic Organ Prolapse - The Role of Prosima. Author: Mark Slack.

ETH.MESH.08156958

ETH.MESH.08161765 - Email from Suzy Taylor to Jared Aldridge, et al. re: Follow up to FDA Mesh Advisory.

ETH.MESH.08167452-453 (Adkins Trial Exhibit P1553)

ETH.MESH.08169582-620 - Surgical Practice of POP survey on Survey Monkey.

ETH.MESH.08290691

ETH.MESH.08299913-917 - Nilsson C. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J 2013; 24(8): 1265-9 [9.11.13 Exhibit T-1271]

ETH.MESH.08307644-645 - 4.05.2013 - Email from P. Hinoul to G. Callen re: RCT data (with attachments).

ETH.MESH.08309057-092 - Document entitled "Benefit-Risk Profile of Ethicon, Inc.'s Pelvic Organ Prolapse Mesh Repair Products."

ETH.MESH.08315779 - Clinical Expert report-09.25.2012

ETH.MESH.08328772-922 - Prosima - Patient Brochure Literature

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### **Production Materials**

ETH.MESH.08334244-245 - Email string re-Photographs of LCM vs MCM with powerpoint attachment

ETH.MESH.08375158-159 - Email string, top one from Larry Gillihan to Kenneth Pagel, Jason Hernandez re: New Product Tabs - TVT Abbrevo, Prosima, TVT Exact.

ETH.MESH.08384247

ETH.MESH.08384270 - Email string, top one from Lisa Pitts to Paul Saliba re: Prosima pearls from Dr. Garris.

ETH.MESH.08421628 - Ethicon Gynecare WW Commercialization Decision - US Customer Discussion Guide 6/1/12

ETH.MESH.08476311 - Cytotoxicity assessment of Ulstem sling

ETH.MESH.08492824 - Strategic Business Team Meeting - Meeting Notes

ETH.MESH.08565137-141

ETH.MESH.08568006-012 - Abstracts Feola 2011 - Abs Stress-shielding: the impact of mesh stiffness on vaginal function (Engleman Trial Exhibit P2564)

ETH.MESH.08640676 - Jones email 4/04/08 re Prosima update for RBDs

ETH.MESH.08791917

ETH.MESH.08945734-735 - ICS-IUGA 2010 Abstract Form. "Ultrasound assessment 6 months following vaginal prolapse surgery using polypropylene implants and a vaginal support device."

ETH.MESH.08945742-744 - Presentation Title: A New Operation for Vaginal Prolapse Repair using Mesh and a Vaginal Support Device: 1 Year Anatomic and Functional Results of an International, Multicentre Study." Presenter: Slack, M., et al.

ETH.MESH.08945836-840 - Document entitled "Gynecare Prosima Claims List."

ETH.MESH.08948364-365 - Email string, top one from Kevin Frost to William Rush re: Save the Date: Prosima 2 Year Clinical Data Review; cc: Tom Affeld.

ETH.MESH.08951725-726 - Email string, top one from Tom Affeld to Kevin Frosr re: Prosima 2 year summary for eClinical Compendium.

ETH.MESH.08961175-176

ETH.MESH.08962682-683 - Email from Helen Wong to Kevin Frost re: Sepulveda's comment on the VRT; cc: Jenny Krieger, et al.

ETH.MESH.08962684-685 - Email string, top one from Jenny Krieger to Kevin Frost re: Reminder: Prosima Teleconference today.

ETH.MESH.08971152-153 - Email string, top one from Kevin Frost to Libby Lewis re: Prosima VRT Invitation plan - due Jan 28.

ETH.MESH.08971269-270 - Email string, top one from Kevin Frost to Aaron Kirkemo, Piet Hinoul re: Prosima VRT: fill-in.

ETH.MESH.08971271-272 - Email string, top one from Kevin Frost to Marilyn Valdes re: Dr. Sepulveda availability on 1/31.

ETH.MESH.08971309-314 - Email string, top one from Kevin Frost to Helen Wong re: Dr. Sepulveda's 1/31 VRT; cc: Jenny Krieger.

ETH.MESH.08988155 - Powerpoint: Gynecare Prosima ™ Pelvic Floor Repair System: Background. Halina Zyczynski, M.D.

ETH.MESH.08988298-417 - EBM - Pelvic Organ Prolapse Clinical References: 2002-2011, including Prolift, Prolift+M, Prosima, Gynemesh. Searcher: Kerry Kushinka.

ETH.MESH.09050450 - Memoradum from David Robinson re: the compatibility if estrogen creams with Prosima balloon and vaginal support device. (Not signed).

ETH.MESH.09100506 - Prolift Professional Education Slide Deck (2005)

ETH.MESH.09128451 - Chart entitled "Faculty Training."

ETH.MESH.09128545 - Pelvic Organ Prolapse Surgical Mesh Discussion call in information 8/25/11

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### **Production Materials**

ETH.MESH.09138054-055 - Information re: Jaime Sepulveda, M.D. and Arthur Mourtzinos, M.D.

ETH.MESH.09142383-384 - Email from Kevin Frost to danhalt@gmail.com, et al. re: Save the Date: Prosima Faculty Conference Call 7/20 at 7pm EST; cc: Jennifer Paradise.

ETH.MESH.09142511 - (Draft) EWHU Memo from Bart Pattyson (US Marketing and Professional Education) to US Faculty Members re: Gynecare Prosima - Pelvic Floor Repair System, Updated Professional Education Deck.

ETH.MESH.09144349 - Powerpoint: Ethicon Women's Health and Urology: Clinical Expertise Road Map.

ETH.MESH.09191424-426 - Email string, top one from Hemangini Patel to Carolina Guzman re: Final Draft report for Prosima - Urgent; cc: Irene Leslie, Rosangela Ribeiro.

ETH.MESH.09207059 - Chart entitled "Grier."

ETH.MESH.09218452-453 - Email string, top one from Rhonda Peebles to Andrew Meek re: Remaining 2010 labs; cc: Kevin Frost, et al.

ETH.MESH.09238537 - TVT Secur 12 month Post Launch Review

ETH.MESH.09264945-946 - Prolene Mesh Re-Design Project

ETH.MESH.09268043-045

ETH.MESH.09283030 - Spreadsheet re: Open Incontinence & AP.

ETH.MESH.09283031 - Spreadsheet re: Open Incontinence & AP.

ETH.MESH.09283032 - Spreadsheet re: Pelvic Floor Repair

ETH.MESH.09283033 - Spreadsheet re: Budget Summary

ETH.MESH.09283034 - Spreadsheet re: Integrated Marketing

ETH.MESH.09283035 - Spreadsheet re: Summary

ETH.MESH.09283036 - Spreadsheet re: Pelvic Floor Repair

ETH.MESH.09283037 - Spreadsheet re: Budget Summary

ETH.MESH.09283038 - Spreadsheet re: Integrated Marketing

ETH.MESH.09290755 - Spreadsheet re: Q1 2012 Open PO Summary

ETH.MESH.09290760 - Spreadsheet re: Open Incontinence & AP.

ETH.MESH.09290767 - Spreadsheet re: Uterine Health

ETH.MESH.09290769 - Spreadsheet re: Ethicon Gynecare May 2012 Open PO Summary

ETH.MESH.09290772 - Spreadsheet re: Budget Summary

ETH.MESH.09300480 - Spreadsheet re: Prosima All Day

ETH.MESH.09625725-729 - Government Submissions Log Sheet

ETH.MESH.09625731-737 - FDA Letter. re: approved drug application for polypropylene suture.

ETH.MESH.09625816 - FDA letter re: receipt of drug application for polypropylene suture.

ETH.MESH.09625817 - Letter to FDA re: new drug application for Polypropylene Suture.

ETH.MESH.09629447-448 - FDA Labeling Approval for Prolene

ETH.MESH.09630649 - 4.26.1973 FDA Letter RE: NDA 16-374 package insert for Prolene.

ETH.MESH.09634081 - Sections 6 re: adverse effects.

ETH.MESH.09634299-303 - FDA Letter re: approval of PMA supplement.

ETH.MESH.09634318 - Prolene Package Insert.

ETH.MESH.09634662-663 - FDA Letter re: reclassification of Nonabsorbable Polypropylene Surgical Suture.

ETH.MESH.09634664-688 - FDA Letter re: reclassification of Nonabsorbable Polypropylene Surgical Suture.

ETH.MESH.09634670 - FDA Reclassification of Nonabsorbable Polypropylene Surgical Suture (July 5, 1990)

ETH.MESH.09656792

### **Production Materials**

ETH.MESH.09656795 ETH.MESH.09744840-845

ETH.MESH.09744848-855

ETH.MESH.09744858-863 - TVT Patient Brochure

ETH.MESH.09746948-998 - License and Supply Agreement [Rosenzweig Exhibit 21 - 12.22.15]

ETH.MESH.09747038-097 - Medscand Agreement

ETH.MESH.09747337-369 - (P041320) TVT Asset Purchase Agreement

ETH.MESH.09888187-223 - Seven Year Data for Ten Year Prolene Study - Plaintiff's Exhibit 4102

ETH.MESH.09908683-702 - 2003 TVT-O Report - IFU Device packaging Adequate by Outside surgeons

ETH.MESH.09911296-299 - Dan Smith email dated 11.13.2008 re things to consider as we assess next steps for a next generation sling (Engleman/Adkins Trial Exhibit P1676)

ETH.MESH.09922570-578 - R&D Memorandum of PA Mesh Assessments for TVTO-PA Revision 1

ETH.MESH.09951746-747 - Scott Ciarrocca email to Katrin Elbert dated 02.27.2009 re minime discussion at the board meeting (Engleman/Adkins Trial Exhibit P1677)

ETH.MESH.10027307-328 - TVT Surgeons Resource Monograph - June 2000

ETH.MESH.10038839 - Gynemesh PS Slide Deck 2004

ETH.MESH.10038844 - The Use of Graft Material in Prolapse Repair - Dr. Sepulveda

ETH.MESH.10048035-036 - Email from Mark Pare to Walter Boldish, et al. re: Clinical #2 - Prosima; cc: Elizabeth David, et al.

ETH.MESH.10179518-636 - Clinical Evaluation Report - Gynecare Gynemesh ™ PS Nonabsorbable Prolene ™ Soft Mesh signed by Piet Hinoul April 26, 2013

ETH.MESH.10220659

ETH.MESH.10224077 - Email string, top one from Molly Dugan to Greg Prine re: Prosima Lab Feedback; cc: Joseph Drabik.

ETH.MESH.10232708 - Email from Stevan Barendse to Greg Prine re: Prosima targets.

ETH.MESH.10281860-874 - Tension-Free Midurethral Sling: Market Update.

ETH.MESH.10376963

ETH.MESH.10378001-002

ETH.MESH.10384309-310

ETH.MESH.10399553-554 - Email from Judi Gauld to Marcus Carey, et al. re: Prosima presentation at AUA; cc: David Robinson, et al.

ETH.MESH.10551392-399

ETH.MESH.10606160 - 2013 TVT Family of Products Clinical Evaluation Report signed by Piet Hinoul 2013

ETH.MESH.10608341-357 - Post Market Surveillance Report. Pelvic Floor Repair Systems. Gynecare Prolift, Gynecare Prolift+M and Gynecare Prosima

ETH.MESH.10686760-771 - Gynemesh PS aFMEA 2013

ETH.MESH.10686833-852 - Risk Management Report (RMR) for Gynemesh PS 2013

ETH.MESH.10817931 - Pelvic Mesh Post-Market Surveillance Orders April 2012

ETH.MESH.10960414 - Email from Christopher O'Hara to François Barbe, et al. re: VRT for Prosima.

ETH.MESH.10977-983

ETH.MESH.11048537-538 - Prosima E-blast No. 1 "The Proof of Success."

ETH.MESH.11335589 - Risk Assessment for TVT Secur 2013.

ETH.MESH.11336474-487 - Ten Year In Vivo Suture Study Scanning Electron Microscopy-5 Year Report -

Plaintiff's Exhibit 4111

ETH.MESH.11448841 - Conference Participant Report 8/25/11

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### **Production Materials**

ETH.MESH.11518663-665 - Email string, top one from Melissa Doyle to Arthur Mourtzinos re: Agenda for tomorrow's lab.

ETH.MESH.11522550-551 - Email string, top one from Melissa Doyle to Seth Moskos re: VSD "take home" instructions.

ETH.MESH.11523079 - Email from Melissa Doyle to Walter Boldish, et al. re: Lahey Labs September 18, 2010; cc: Carole Carter-Cleaver.

ETH.MESH.11524125-128 - Email string, top one from Melissa Doyle to Andrew Meek re: Upcoming Labs - planning.

ETH.MESH.11536046 - Email string, top one from Jonathan Fernandez to Rhonda Peebles re: Remaining 2010 labs; cc: Robert Zipfel, et al.

ETH.MESH.11538048-049 - DX24787 - Frost email re Prosima useage

ETH.MESH.11543641 - Powerpoint GYNECARE GYNEMESH\* PS Nonabsorbable PROLENE\* Soft Mesh Awareness Module

ETH.MESH.11543719 - Robinson Gynemesh PS Presentation Awareness Module 4.7.04

ETH.MESH.11905619 - Spreadsheet: Prosima Virtual Roundtable Calls & Targets

ETH.MESH.1210987-995

ETH.MESH.1222075-079 - Letter to Weisberg/Robinson re: Elongation Characteristics of Laster Cut PROLENE Mesh for TVT, from Kammerer

ETH.MESH.12227301

ETH.MESH.12831391-392 - P4128 - IR Microscopy of Explanted Prolene received from Prof. R. Guidoin.

ETH.MESH.12897617-678 - Clinical Evaluation Report - Prosima ™ signed by Piet Hinoul.

ETH.MESH.13204537 - MDD Resolution Form

ETH.MESH.13314554 - Email from Laura Hance to Dr. Lowden re: Prosima answer to JP drain and hydrodissection.

ETH.MESH.13532200 - Ethicon Gynecare WW Commercialization Decision - US Sales Call Script 6/1/12

ETH.MESH.13577809-810 - Prosima Virtual RoundTable

ETH.MESH.13582263 - Reisenauer Prosima study

ETH.MESH.13589382 - Prosima Sales Aid 2

ETH.MESH.13589382 - Prosima Sales Aid 3

ETH.MESH.13589382 - Prosima Selling Guide

ETH.MESH.13592561 - Prosima Trainee Invitation "Advanced Pelvic Floor Course with Gynecare Prosima"

ETH.MESH.13596052 - Prosima Sales Aid 4 (Proof)

ETH.MESH.13600015 - Barber Study - Defining Success After Surgery for POP

ETH.MESH.13618003-004 - EWHU eClinical Compendium - Article Summary. Reisenauer, C., et al. "Anatomic study of prolapse surgery with nonanchored mesh and a vaginal support device."

ETH.MESH.13618029-031 - EWHU eClinical Compendium - Article Summary. Zyczynski, H.M., et al. "One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device."

ETH.MESH.13622000-070 - Prosima Trainee Deck Distribution

ETH.MESH.13626471 - Prosima Sales Aid 7 (Proof of Success)

ETH.MESH.13627691 - Expert interview with Dr. Carey (clean)

ETH.MESH.13635675 - 2011 B&W POP & SUI Patient Counseling Guide

ETH.MESH.13635675-696 - Pelvic Organ Prolapse Patient Counseling Guide (2011)

ETH.MESH.13637531 - Prosima presentation background and development history

### **Production Materials**

ETH.MESH.13645631 - DVD - Thoughts on Prolift+M and Prosima from Drs. Michel Cosson and Marcus Carey.

ETH.MESH.13649510 - Prosima Sales Training Program

ETH.MESH.13650207 - Prosima Sales Aid Brochure (Dance)

ETH.MESH.13670432 - Prosima Key Procedural Steps (double-sided)

ETH.MESH.13697383 - Prosima legal manufacturer Ethicon Sarl

ETH.MESH.13698543 - Prosima Marketing Material Roll-Out Letter.

ETH.MESH.13698840-859 - Bart Pattyson editorial re prof ed bulletin

ETH.MESH.13699623 - Prosima sales training points

ETH.MESH.13699656 - Prosima DVD

ETH.MESH.13699656 - Prosima Sales Rep materials

ETH.MESH.13699656 - Prosima video with Van Drie and Grier.wmv

ETH.MESH.13699674-754 - Clinical Study Report: A Prospective, Multi-centre Study to Evaluate the Clinical Performance of the Gynecare Prosima ™ Pelvic Floor Repair System as a Procedure for Pelvic Organ Prolapse.

ETH.MESH.13713001 - Good image of Prosima box

ETH.MESH.13718001 - Prosima Objective Success Learning Guide

ETH.MESH.13718497 - Prosima Patient Brochure 2

ETH.MESH.13724290 - Prosima Apical Support Learning Guide

ETH.MESH.13726909 - Prosima Key Points

ETH.MESH.13727241 - Prosima Overview Presentation

ETH.MESH.13733674 - Prosima MRI Image and Sales Aid

ETH.MESH.13756212-218 - Clinical study Finding Discussion for Gynecare Prosima ™ Pelvic Floor Repair System by Piet Hinoul (Audio Transcript).

ETH.MESH.13756219 - Gynecare Prosima ™ Pelvic Floor Repair System MRI Address

ETH.MESH.13756384 - Prosima Virtual Round Table Trainee Confirmation

ETH.MESH.13756409 - Prosima Virtual Round Table Preceptor Follow-up and Invitation.

ETH.MESH.13756416-417 - Prosima Virtual Round Table Preceptor Confirmation.

ETH.MESH.13869166 - Powerpoint: Mint Project - Pelvic Floor Repair.

ETH.MESH.13907284 - Power Point - Particles in TVT-O Blisters

ETH.MESH.14020602 - Dr. Gregory Bolton email to Kathy Hampton dated 09.05.2007 re TVT Secur (Engleman Trial Exhibit P1769)

ETH.MESH.14415283-286

ETH.MESH.14427453-455 - FDA Clearance Letter re: K063562 Gynecare Prosima ™

ETH.MESH.14427459-543 - Letter to FDA re: 510(k) K063562 S1, response to deficiencies email.

ETH.MESH.14427562-563 - Memo to Prosima Regulatory File. Minutes from Teleconference with FDA for Prosima 510(k).

ETH.MESH.14427564-565 - FDA Letter re: K063562 Gynecare Prosima Premarket Notification 510(k)

ETH.MESH.14427567-569 - Email from Nada Hanafi to Patrice Napoda re: K063562 Gynecare Prosima.

ETH.MESH.14427578-761 - Traditionsl 510(k) Premarket Notification Gynecare Prosima ™ Pelvic Floor Repair System.

ETH.MESH.14901753 - Batch Review Lot #3405428 Complaint PI1

ETH.MESH.15057318 - Dr. David Robinson memo analysis dated 02.23.2006 re elongation characteristics of laser-cut Prolene mesh for TVT Secur

ETH.MESH.15958178-182 Email string, top one from Brian Luscombe to Tom Affeld re: Approved for distribution: FDA Notification FAQS and Customer Letter.

ETH.MESH.161953-954 - Gynecare TVT Obturator System Sales Materials

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### **Production Materials**

ETH.MESH.16259973 - Email from Lisa Jannone dated 1/5/12 re message from Lesley Fronio re update on recent media reports

ETH.MESH.16262740 (2004)

ETH.MESH.16350627-628 - Email string, top one from Piet Hinoul to Paan Hermansson re: key message for upcoming Prosima launch.

ETH.MESH.16352932-934 - Email from Paan Hermansson to Sonja Willems, et al. re: Great EWH&U success at ICS/IUGA congress in Toronto; cc: Bernhard Fischer, et al.

ETH.MESH.1751069-094 - 09/07/2009 Safety review: TVT and TVT-O procedures

ETH.MESH.17669942 - Email from Robert Zipfel tp Elizabeth David, et al. re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones and Schlafstein on Monday Jan 4, 2010.

ETH.MESH.17748760-761 - E-mail from Kevin Frost regarding 2011 Incontinence & Pelvic Floor Recap

ETH.MESH.1784779-782 - Memo re: TVT-Base & TVT-O Complaint Review for Laser Cut Mesh (LCM) Risk Analysis

ETH.MESH.1784823-828 - 2006 TVT TVTO Laser Cut Clinical Expert Report

ETH.MESH.1809056-058

ETH.MESH.1809080-081 - Memo re: Comparison of Laser-cut and machine-cut TVT Mesh to Meshes from Competetive Devices (BE02004-1641)

ETH.MESH.1815660-664 - Project Mulberry, Preliminary Clinical Diligence Report ]

ETH.MESH.18844812 - Email from Patrick Kaminski to Robert Zipfel re: Dr. Thomas Antonini; cc: Stevan Barendse re delaying launch.

ETH.MESH.19308264-265 - Email from Walter Boldish to Stefanie Garbarino re: Prosima cadaver labs.

ETH.MESH.19310234-238 - Email string, top one from Stefanie Garbarino to Dr. Maxwell re: TVT-O

ETH.MESH.19804279-286

ETH.MESH.222852-863 - 12/15/2003, Gynecare Final Report # 03\*0740, TVT Obturator System

ETH.MESH.222899-909

ETH.MESH.2236604-609 - TVT Obturator Brochure; "Results, Precision & Proven Mesh"

ETH.MESH.223779-784 - Risk Management Report, TVT Laser Cut Mesh (LCM). Document Number RMR-0000017, Rev. 3

ETH.MESH.22625140-145 - MDD CAPA # CAPA-003474

ETH.MESH.22631022-2029 - TVT - Response to Section 39 Request, D-1, 1-1002

ETH.MESH.2293715-716

ETH.MESH.2340504-533 - TVT IFU

ETH.MESH.2340902-908

ETH.MESH.25576110 - 30 Proceed studies from 2016.10.00 Proceed CER Rev. 6\_Schmitz.Day.Lin

ETH.MESH.262089-123 - Manuscript Draft: (de Leval) Novel surgical technique for the treatment of female stress urinary incontinence: Transobturator Vaginal Tape Inside-Out

ETH.MESH.3364663-666

ETH.MESH.3365250-251

ETH.MESH.341006-011 - 11/11/10 Letter from John Young re: Global Regulatory Strategy for TVT IFU (RMC P15506/E) Update (Part II, RA0001-2010, Rev. 1)

ETH.MESH.3427878-883 - TVT IFU

ETH.MESH.371496-594 - 01/28/98 Letter from FDA re: K974098 TVT System

ETH.MESH.3922926-928

ETH.MESH.3932909-911 - History of TVT-O

## **Production Materials**

ETH.MESH.3934952-967 - Tension-Free Vaginal Obturator Tape (TVOT) - April 30, 2003 - Meeting Report
ETH.MESH.3939167-171 - Waltregny (2006) Inside Out Transobturator Vaginal Tape for the Treatment of Female Stress Urinary Incontinence: Interim Results of a Prospective Study After a 1-Year Minimum Followup
ETH.MESH.4048515-520 - KOL Interview
ETH.MESH.4384126-165
ETH.MESH.442825-826
ETH.MESH.524746-748
ETH.MESH.525573
ETH.MESH.5315252-265 - Final Report, PSE Accession No. 97-0197, Project No. 16672
ETH.MESH.658177-198 - Surgeon's Resource Monograph, A Report of the June 2000 Summit Meeting
ETH.MESH.6696411-419
ETH.MESH.6859834-835
ETH.MESH.6878438-439 - Memo re: VOC on new Laser Cut TVT Mesh
ETH.MESH.6882641-642
ETH.MESH.6886410-411
ETH.MESH.7393700 - 05/13/2003 Memo to Gynecare Continence Health Sales Team re: Gynecare TVT Physician
Training Policy
ETH.MESH.7692905-907
ETH.MESH.8003295-301 - Patient Brochure: "Stop coping, start living."
ETH.MESH.8003303-317 - Patient Brochure: "Stop coping, start living."
ETH.MESH.823793-806 - Transobturator Vaginal Tape Inside-Out (TVT-O): From Development to Clinical
Experience
ETH.MESH.865069-072
ETH.MESH.PM.000001
ETH.MESH.PM.000003
ETH.MESH.PM.000004
ETH.MESH.PM.000006
ETH.MESH.PM.000007
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## **Production Materials**

Froduction Waterials
ETH.MESH.PM.000048
ETH.MESH.PM.000057
ETH.MESH.PM.000058
ETH.MESH.PM.000059
ETH.MESH.PM.000065 - Prolift Professional Education Videos
ETH.MESH.PM.000068
ETH.MESH.PM.000075 - Prolift Professional Education Videos
ETH.MESH.PM.000076 - Prolift Professional Education Videos
ETH.MESH.PM.000078 - Prolift Professional Education Videos
ETH.MESH.PM.000083
ETH.MESH.PM.000084
ETH.MESH.PM.000087
ETH.MESH.PM.000088 - Anatomy Videos
ETH.MESH.PM.000089 - Anatomy Videos
ETH.MESH.PM.000090 - Anatomy Videos
ETH.MESH.PM.000092 - Prolift +M Professional Education Videos
ETH.MESH.PM.000093
ETH.MESH.PM.000094
ETH.MESH.PM.000095
ETH.MESH.PM.000096
ETH.MESH.PM.000097
ETH.MESH.PM.000098
ETH.MESH.PM.000130
ETH.MESH.PM.000134 - Anatomy Videos
ETH.MESH.PM.000143
ETH.MESH.PM.000145 - Prolift +M Professional Education Videos
ETH.MESH.PM.000148
ETH.MESH.PM.000151 - Anatomy Videos
ETH.MESH.PM.000154 - Anatomy Videos
ETH.MESH.PM.000156
ETH.MESH.PM.000157
ETH.MESH.PM.000170
ETH.MESH.PM.000171
ETH.MESH.PM.000179 - TVT Secur IFU V5e 2005 to disc (Original from Prof Ed DVD)
ETH.MESH.PM.000179 - TVT-Secur Key Tech Points 5.24.2007 (Color Oringinal from Prof Ed DVD)
ETH.MESH.PM.000190 - Prolift Professional Education Videos
ETH.MESH.PM.000192 - Prolift Professional Education Videos
ETH.MESH.PM.000202
ETH.MESH.PM.000246
ETH.MESH.PM.000257
ETH.MESH.PM.000272
ETH.MESH.PM.000273
ETH.MESH.PM.000274
ETH.MESH.PM.000288
ETH.MESH.PM.000303
ETH.MESH.PM.000306
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ETH.MESH.PM.000316	
ETH.MESH.PM.000317	
ETH.MESH.PM.000318	
ETH.MESH.PM.000319	
ETH.MESH.PM.000320	
ETH.MESH.PM.000321	
ETH.MESH.PM.000322	
ETH.MESH.PM.000336	

ETH.MESH-12897617-678 - 2013 Clinical Evaluation Report; Gynecare Prosima Pelvic Floor Repair System

ETH-00254-261

ETH-00295-300

ETH-00797-829 - 510(k) Notification Gynemesh Prolene ™ Soft Nonabsorbable Synthetic Surgical Mesh.

ETH-00807-808 - FDA Clearance letter for Gynemesh soft mesh for pelvic floor repair

ETH-00830-861 - Labeling/Package Insert

ETH-00862-893 - Test Method for the Determinartion of Mesh Burst Strength for Prolene Soft Mesh.

ETH-00894-927 - Medical Literature

ETH-01363-365 - Letter to Bryan Lisa from Mark M. Melkerson

ETH-01816-817 - FDA Clearance Letter, Prolene Soft Mesh (K001122)

ETH-02386 - Cosson, M. Prospective Clinical Assessment of the Total Vaginal Mesh (TVM) Technique for Treatment of Pelvic Organ Prolapse - 6 and 12 month results

ETH-02387 - Lucente, V. Prospective clinical assessment of the total vaginal mesh (TVM) Technique for treatment of pelvic organ prolapse - 6 and 12 month results.

ETH-02388 - Amblard, J. From the TVM to the Prolift® (Gynecare): evolution of a technique for prosthetic support to treat prolapse via the vaginal route, concerning a retrospective multicentric series of 794 patients (684 TVM/110 Prolift)

ETH-02653 - Fatton, B. Preliminary results of the "Prolift™" Technique in the treatment of pelvic organ prolapse by vaginal approach: a multicentric retrospective series of 110 patients. IUGA 2006 Athens Non-discussed Abstract 275

ETH-02750-755 - Hinoul P. A Prospective Study to Evaluate the Anatomic and Functional Outcome of a Transobturator Mesh Kit (Prolift Anterior) for Symptomatic Cystocele Repair. Journal of Minimally Invasive Gynecology (2008) 15, 615-620

ETH-03220-221 - Cosson, M. Preservation of uterus when treating prolapse by Prolift TM does not significantly reduce risk of early post-surgical complications and failures. ABS 89

ETH-03223 - Dedet, B. Transvaginal repair of genital prolapse by the Prolift technique: outcome one year after surgery.

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ETH-37788-793 - Gynecare Prolift Clinical Expert report

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Randomized Controlled Trial. Obstet Gynecol 2007;110-455-62

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 $Ethicon\ Women's\ Health\ \&\ Urology\ -\ Clinical\ Compendium\ -\ Sales\ Rep\ Positioning\ [ETH.MESH.0011879;$ 

ETH.MESH.00093830]

Ethicon's TVT Secur Postmarket Surveillance Study Plan: {S120095; Gynecare TVT Securm System

[ETH.MESH.04474733]

EWHU Faculty and PF User Conference Calls Outline

FDA response to Discontinuation Plan

Get the facts, be informed, make your best decision

Guidance for Industry and FDA Staff. "Class II Special Controls Guidance Document: Surgical sutures; Guidance for Industry and FDA."

Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance. "Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh."

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Gynecare TVT Tension-free Support for Incontinence: Professional Education Slides

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JJM.Mesh.00043703 Response Statement and FAQS - FDA Notification about use of surgical mesh to treat
pelvic organ prolapse and stress urinary incontinence
Johnson & Johnson - Our Credo [8.9.13 A.M. Mitchell Exhibit T-3134]
June, 2009 Klosterhalfen intermediate report on explanted mesh (highlighted)
K013718 GYNEMESH PS (Ethicon) Corrected SE Letter (07-Nov-2012)
Key Gynemesh PS Study - Jacuqetin, et al. Prolene Soft Mesh for POP Surgical treatment
Klinge Presentation PVDF: a new alternative? Meeting o Hernia Experts Exhibit P-1944
Letter from Dr. Joerg L. Holste, re: Biocompatibility Risk Assessment for Laser-cut Implant of Gynecare TVT
Letter from Dr. Joerg L. Holste, re: Biocompatibility Risk Assessment for Laser-cut Implant of Gynecare TVT (2.2.2006)
Letter from FDA re: Postmarket Surveillance (PS) Study: PS120044 (Prosima 522 Order)
Letters to and from the FDA re: Prolene, Polypropylene Nonabsorbable Surgical Suture, USP.
Librojo Declaration
Librojo updated TVT Declaration (10-23-15) [12 pages]
Lucente - Prospective Clinical Assessment of the TVM technique
May 15, 2008 510(K) Summary of Safety and Effectiveness
May 2010 CER for Gynemesh PS signed by David Robinson
McCabe email re - Sheath Sales Tool - 464
Memo from Kammerer/ Silimkhan re: Ultrasonic Slitting of PROLENE Mesh for TVT (11.25.2002)
Memo to S. Ciarrocca re: Regulatory Strategy - Project D'Art; Rev 3
Mesh Information for Patients with Pelvic Floor Disorders
Mesh POP Gynemesh Prolift Slides
Mesh SUI TVT Slides
MSDS-Marlex Polypropylenes
Notice of Claimed Investigational Exemption for a New Drug (1-125)
Notice of Claimed Investigational Exemption for a New Drug (126-253)
P041156 - Chart referencing Prolene TVT as microporous
P041206 - Presentation - Gadot Incontinence Marketing Platform
P041239 - Email from Gauld email re: Prosima/TVT World
P041319 - Email from Lehe re: Prolene mesh in TVT 1999
P041353 - Email from Angelini re: Prof. Klutke technique concern
P041355 - Email from Hoepffner re: TVT brainstorming meeting
P041356 - Email from Godwin re: Wang report - TVT
P041358 - TVT-O Licensing Agreement
P041380 - Dan Smith 2003 - TVT-O
P041382 - Email from Dan Smith re: Mulbuerry Update - TVT-O
P041384 - Email from Toddywala re: Project Mulberry - TVT-O
P041389 - Email from Waltregny re: 2003 IFU
P041392 - Email from Dan Smith re: TVT-O
P041500 - Email from Nichols re: TVTx Charter document
P041523 - Email from Arnaud re: Kammerer email re: TVT/TVT-O
P041572 - Email from Urquhart re: TVT World AE Report data
P041576 - TVT World Presentation
P045337 - Margolis invoices

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Prosima training deck 2

PS120046 A2 - 7.9.12 FDA Response to Ethicon re Gynemesh PS

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Schumpelick - Hernia Repair Sequelae (Engleman Trial Exhibit P1918)

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Slide Presentatopm "Gynecare Prosima ™ Pelvic Floor Repair System

Supplement Numbers and Application Dates

Surgeon's Resource Monograph

T-3326 - Email from Chen re: TVT IFUs

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TVT and TVT-O IFU

TVT Exact IFU - 01.2015

TVT IFU - 01.2015

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[ETH.MESH.05222673-705] [ETH.MESH.02340306-69] [ETH.MESH.02340471-503] [ETH.MESH.02340504-67]

[ETH.MESH.03427878-945] [ETH.MESH.05225354-85]

TVT O IFU [ETH.MESH.2340902-8]

TVT Patient Brochure - 2015

TVT Patient Brochures:

[ETH.MESH.00144270-8] [ETH.MESH.00160615-25] [ETH.MESH.00658421-9] [ETH.MESH.01613143-46]

[ETH.MESH.03458123-38] [ETH.MESH.03459088-104] [ETH.MESH.06087471-2] [ETH.MESH.06087513-4]

[ETH.MESH.08003173-80] [ETH.MESH.08003181-96] [ETH.MESH.08003197-212] [ETH.MESH.08003215-30]

[ETH.MESH.08003231-46] [ETH.MESH.08003247-62] [ETH.MESH.08003263-78] [ETH.MESH.08003279-94]

[ETH.MESH.08003295-302] [ETH.MESH.08003303-18] [ETH.MESH.09744840-ETH.MESH.09744845]

[ETH.MESH.09744848-ETH.MESH.09744855] [ETH.MESH.09744858-ETH.MESH.09744863]

**TVT Secur IFU** 

TVT Secur Professional education

TVT Secur Surgical Technique Guide

TVT, TVT-O, Gynemesh and Prolift IFU

TVT, TVT-O, Gynemesh and Prolift Professional education.

**TVT-Abbrevo Company Documents** 

TVT-O IFU [ETH.MESH.00860239-310]

TVT-O IFU [ETH.MESH.2340902-908]

TVT-O IFUs:

[ETH.MESH.02340756-828] [ETH.MESH.02340829-901] [ETH.MESH.02340902-73] [ETH.MESH.02340974-1046]

TVT-O la bandelette trans-obturatrice (Photograph)

TVT-Obturator IFU - 01.2015

Use of Gynemesh PS in Prolapse Surgery 000001 4275674 d

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## **Company Witness Depos**

· · ·
Deponent [Date of Deposition]
Angelini, Laura [09.16.2013]
Angelini, Laura [09.17.2013]
Angelini, Laura [11.14.2013]
Arnaud, Axel [11.15.12]
Arnaud, Axel [11.16.12]
Arnaud, Axel [7.19.2013]
Arnaud, Axel [7.20.2013]
Arnaud, Axel [9.25.2013]
Austin, Charles E 08.13.2015
Barbolt, Thomas [1.7.2014]
Barbolt, Thomas [1.8.2014]
Barbolt, Thomas [8.14.2013]
Barbolt, Thomas [8.15.2013]
Barbolt, Thomas Ph.D. [10.10.12]
Barbolt, Thomas Ph.D. [10.9.12]
Batke, Boris [8.1.2013]
Batke, Boris [8.2.2013]
Beach, Patricia [6.17.13]
Beath, Catherine [11.8.12]
Beath, Catherine [11.9.12]
Beath, Catherine [3.26.12]
Beath, Catherine [3.27.12]
Beath, Catherine [7.11.2013]
Beath, Catherine [7.12.2013]
Brown, Allison [9.11.13]
Burkley, Dan F [5.22.2013]
Burkley, Dan F [5.23.2013]
Burkley, Daniel [10.2.12]
Cecchini, Peter [10.22.2013]
Cecchini, Peter [10.23.2013]
Chahal, Ricky [12.10.2014]
Chen, Meng [10.29.2013]
Chen, Meng [10.3.12]
Chen, Meng [10.30.2013]
Chen, Meng [10.4.2012]
Courts, Paul [6.11.15]
Elbert, Katrin [12.23.14]
Elbert, Katrin, Ph.D. [12.23.2014]
Gauld, Judith [11.8.13] [4.27.12]
Grier, Douglas [12.30.2014]
Hart, James [12.20.13]
Hart, James [9.17.13]
Hart, James [9.18.13]
Hellhammer, Brigitte [9.11.2013]
Hellhammer, Brigitte [9.12.2013]
Hinoul, Piet - 01.13.2014 Deposition Testimony

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## **Company Witness Depos**

Hinoul, Piet - 01.14.2014 Deposition Testimony
Hinoul, Piet - 01.15.2014 Deposition Testimony
Hinoul, Piet - 06.26.2013 Deposition Testimony
Hinoul, Piet - 06.27.2013 Deposition Testimony
Hinoul, Piet - 09.18.2012 Deposition Testimony
Hinoul, Piet M.D., Ph.D. [4.5.12]
Hinoul, Piet M.D., Ph.D. [4.6.12]
Hinoul, Piet M.D., Ph.D. [9.18.12]
Hinoul, Piet M.D., Ph.D. [9.19.12]
Holste, Joerg [12.14.12]
Holste, Joerg [12.15.12]
Holste, Joerg [7.29.2013]
Holste, Joerg [7.30.2013]
Horton, Ronald, M 07.01.2015
Isenberg, Richard [11.05.2013]
Isenberg, Richard [11.06.2013]
Jones, Gregory R [8.20.2013]
Kammerer, Gene [01.17.2014]
Kammerer, Gene [01.28.2014]
Kammerer, Gene [01.30.2014]
Kammerer, Gene [10.17.12]
Kammerer, Gene [12.03.2013]
Kammerer, Gene [12.05.2013]
Kammerer, Gene [6.12.2013]
Kanerviko, Brian [8.23.13] [8.22.13]
Kirkemo, Aaron [01.06.2014]
Kirkemo, Aaron [01.07.2014]
Kirkemo, Aaron [4.18.12]
Lamont, Dan [4.3.2013]
Lamont, Dan [4.4.2013]
Lamont, Dan [9.10.2013]
Lamont, Dan [9.11.2013]
Lamont, Daniel [4.4.12]
Lamont, Daniel [5.24.12]
Lin, Susan [3.12.2013]
Lin, Susan [3.13.2013]
Lin, Susan [5.2.2013]
Lin, Susan [5.3.2013]
Lin, Susan [8.1.2013]
Lisa, Bryan [12.19.11]
Lisa, Bryan [12.20.11]
Lisa, Bryan A [4.25.2013]
Lisa, Bryan A [4.26.2013]
Luscombe, Brian [7.29.13]
Mahmoud, Ramy [7.15.2013]
Mahmoud, Ramy [7.16.2013]
Meek, Jonathan [2.24.12] [9.11.12]

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Nager, Charles - 06.10.2014 Deposition Testimony
Owens, Charlotte [6.19.2013]
Owens, Charlotte [6.20.2013]
Owens, Charlotte M.D. [9.12.12]
Owens, Charlotte M.D. [9.13.12]
Parisi, Paul [6.6.13]
Peebles, Rhonda [07.16.2014]
Peebles, Rhonda [08.20.2014]
Robinson, David [7.24.2013]
Robinson, David [7.25.2013]
Robinson, David [9.11.2013]
Robinson, David M.D. [3.13.12]
Robinson, David M.D. [3.14.12]
Robinson, David M.D. [8.23.12]
Schmid, Tim - 07.31.2015
Selman, Renee Elayne [6.20.2013]
Selman, Renee Elayne [6.21.2013]
Smith, Dan J [2.3.2014]
Smith, Dan J [2.4.2014]
Smith, Dan J [5.15.2013]
Smith, Dan J [5.16.2013]
Smith, Dan J [6.4.2013]
Smith, Dan J [6.5.2013]
Smith, Dan J [8.20.2013]
Smith, Dan J [8.21.2013]
St Hilaire, Price [7.11.13]
Vailhe, Christophe [6.20.13]
Vailhe, Christophe [6.20.2013]
Vailhe, Christophe [6.21.2013]
Volpe, Clifford [2.28.12] [2.29.12]
Walji, Zenobia [3.7.12]
Weisberg, Martin - 05.24.2012 Deposition Testimony
Weisberg, Martin - 05.31.2013 Deposition Testimony
Weisberg, Martin - 08.09.2013 Deposition Testimony
Weisberg, Martin - 11.12.2015 Deposition Testimony
Weisberg, Martin - 11.13.2015 Deposition Testimony
Weisberg, Martin - 8.9.2013 Deposition Testimony
Weisberg, Martin [5.30.2013]
Yale, Mark [4.17.12]
Yale, Mark [5.16.12]
Yale, Mark [8.7.2013]
Yale, Mark [8.8.2013]
Zaddern, Vincenzo [3.27.12] [3.28.12]

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### **Publically Available**

21 C.F.R. Part 801(c)

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ACOG (2009) - Committee Opinion: Informed Consent (Number 439)

ACOG (2009) - Committee Opinion: Patient Safety in Obstetrics and Gynecology (Number 447)

ACOG (2011) - Committee Opinion: Tobacco Use and Women's Health (Number 503)

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AUA Patient Guide: 1 in 3 women experience Stress Urinary Incontinence.

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AUGS/SUFU Frequently Asked Questions by Patients: Mid-urethral slings for stress urinary incontinence (March 12, 2014)

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AUGS/SUFU Frequently Asked Questions by Providers MUS for SUI

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Brief Summary of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee [02.25.2016]

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### Other Materials

Communications within the pelvic floor surgical community in 2008, 2011 and 2012 relating to the FDA notices, committee meetings, orders and other developments concerning the use of synthetic mesh and other surgical approaches to pelvic organ prolapse repair

Defense Cross of Weber Slide 12.08.15 Retracted Statement Regarding Nature of POP Surgery

Device Labeling. 21 CFR 801.109(c)

Documents proposed by Plaintiff's counsel to be stipulated to as business records

EAU Guidelines on Urinary Incontinence (Partial Update March 2015)

EAU Pocket Guidelines - Urinary Incontinence (2013)

EU Commission Fact Sheet - (based on 2015 SCENIHR Report) The safety of surgical meshes used in Urogynecological surgery.

FDA 24-Hour Summary: Obstetrics & Gynecology Devices Panel [September 8-9, 2011]

FDA Device Labeling Guidance #G91-1 (blue book memo)

FDA Device Labeling Guidance #G91-1 [March 1991]

FDA Device Labeling Guidance Blue Book [March 1991]

FDA Executive Summary: Reclassification of Urogynecologic Surgical Mesh Instrumentation 2.26.2016 Gastroenterology-Urology Medical Devices Advisory Committee Panel

FDA Executive Summary: Surgical Mesh for Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence - Obstetrics & Gynecology Devices Advisory Committee Meeting (September 8-9, 2011)

FDA Information on Surgical Mesh for Hernia Repairs (2008)

FDA Information on Surgical Mesh for Pelvic Organ Prolapse and Stress Urinary Incontinence (2008)

FDA News Release: Surgical Placement of mesh to repair pelvic organ prolapse poses risk [07.13.2011].

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Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update Appendices A11 and A16.

http\_\_\_www.voicesforpfd - AUGS Patient Information: Mesh Information for Patients with Pelivic Floor Disorders

ICS Abstract 560 - A trocar-free procedure for vaginal prolapse repair using mesh and a vaginal support device - an observational registry. (2011)

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### Other Materials

ICS Abstract 571 - Clinical Outcomes of an Observational Registry Utilizing a Trocar-Guided Mesh Repair of Vaginal Prolapse Using Partially Absorbable Mesh. (2010)

ICS Fact Sheet (2015)

ICS Fact Sheet on Stress Urinary Incontinence. (2011)

ICS Fact Sheets: A Background to Urinary and Faecal Incontinence - prepared by the Publications & Communications Committee, July 2013

ICS Factsheets - SUI - p13 Miduretheral sling the choice (2013)

ICS, IUGA, ACOG, AUGS, AUA, SUFU Groups reaffirm position on use of vaginal mesh for surgical treatment of stress urinary incontinence (2016 August)

International Continence Society Stress Urinary Incontinence Fact Sheet (2013)

International Urogynecological Assocation: The Usage of Grafts in Pelvic Reconstructive Surgery Symposium 2005 July 8-10, 2005, Lago Mar Resort, Fort Lauderdale, FL, USA. Int Urogynecol J 2006; 17: S1-55

IUGA Anterior Vaginal Repair (Bladder Repair)

IUGA Brochure: Vaginal repair with mesh.

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IUGA Mid-urethral sling (MUS) procedures for stress incontinence (2011)

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IUGA Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence (2014 July)

IUGA Poster - Clinical experience of a novel vaginal support device and balloon used to simplify mesh augmented vaginal surgery for prolapse. (Slack, M.)

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Reclassification of Urogynecologic Surgical Mesh Instrumentation FDA Questions - Gastroenterology and Urology Devices Panel of Medical Devices Advisory Committee 2.26.2016

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### Other

02.01.2012 Prosima 522 cover letter

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2009 AUA Prosima Slide - A new operation for vaginal prolapse repair using mesh and a vaginal support device: 1 year anatomic and functional results of an international, multicenter study. (Zyczynski, H.)

2009 IUGA Prosima Slide - A new operation for vaginal prolapse repair using mesh and a vaginal support device: 1 year anatomic and functional results of an international, multicenter study. (Slack, M.)

### 21 CFR Part 801

Barber Summary Positioning Prosima- Ethicon Women's Health & Urology eClinical Compendium- Article Summary [3 pages]

Boukerou Summary Positioning Prosima- Ethicon Women's Health & Urology eClinical Compendium- Article Summary [3 pages]

Clinical Study Findings Discussion for GyneCare Prosima™ Pelvic Floor Repair System by Piet Hinoul PROS-436-10-9/12- Prosima Audio File of 2 year Data [7 pages]

Code of Federal Regulations Title 21, as of 4/1/15. 21CFR801.109

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Demonstrative - Ethicon Powerpoint - Almost uniformly, physicians did not express a preference for company name (Engleman trial exhibit)

Demonstrative - Ethicon powerpoint - Next generation slings - evaluating opportunities, considering risks (Engleman trial exhibit)

Demonstrative - Powerpoint - Warning regarding FBR inflammatory response (pgs 18, 22-27)(Engleman trial exhibit)

Deposition Subject Matter-Design and Development of Mesh Products

**Device Labeling Guidance** 

DVD- Thoughts on Gynecare Prolift+M™ and Gynecare Prosima™ from Drs. Michel Cosson and Marcus Carey

Excerpts from Budke trial transcript (Day 4, 01.08.2015).

FDA 510k Clearance (K181151) - TVT-O and TVT Abbrevo Obturator (2018.08.10)

Gynecare Prosima Clinical Study Investigator Meeting Qualitative Feedback Analysis [15 pages]

Gynecare Prosima content for ethicon360.com [5 pages]

Gynecare Prosima updates to ethicon360.com PROS-314-11-8/12 [113 pages]

Gynecare Prosima VSD Patient Brochure 2009: Stop Coping, Start Living. [2 pages]

Gynecare Prosima VSD Patient Information Slim-Jim: What you should know about the Gynecare Prosima Vaginal Support Device; Stop Coping. Start living™ [2 pages]

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### Other Materials

Gynecare Prosima™ AIDiNC Selling Guide- Your Guide to Selling Gynecare Prosima™ with the AIDiNC process [16 pages]

Gynecare Prosima™ Pelvic Floor Repair System MRI Address PROS-437-10-9/12- Prosima Audio File of MRI Flashcard [1 page]

Gynecare Prosima™ Pelvic Floor Repair System- Objective Success Learning Guide & Key Steps for Success [37 pages]

Gynecare Prosima™ Pelvic Floor Repair System Preceptorship Invitation [1 page]

Gynemesh PS white paper

Prosima 2011 Sales Aid- What Could a Truly Tension-Free Repair Mean for you and your Patients? [20 pages]

Prosima 522 Order

Prosima Apical Support Learning Guide [2 pages]

Prosima E-Blast No. 1- The Proof of Success [2 pages]

Prosima Launch Sales Aid- Your Proof: Her dance class [3 pages]

Prosima Marketing Material Roll-out Letter from Kevin Forst PROS-040-10-2/12 February 16, 2010 [1 page]

Prosima MRI Flashcard 2- Gynecare Prosima™ Pelvic Floor Repair System. The first fixationless mesh system that maintains anatomical position. [2 pages]

Prosima MRI Flashcard- MRI Flashcard Learning Guide [2 pages]

Prosima NTM Opening Presentation 2011- "This Year Prosima is Personal" [8 pages]

Prosima Pelvic Model

Prosima Preceptor Confirmation- Virtual Round Table October 2010 [2 pages]

Prosima Preceptor Follow Up and Invite-Virtual Round Table October 2010 [1 page]

Prosima Prof Ed Deck 2011 [71 pages]

Prosima Prof Ed Deck October 2009 [21 pages]

Prosima Revised Webinar Deck- [21 pages]

Prosima Sales Aid Training Deck- "What could a truly tension-free repair mean for you and your patients?" [5 pages]

Prosima Testimonal for NTM 2010 Video

Prosima Touch Workshop Key Takeaway [2 pages]

Prosima Trainee Confirmation- Virtual Round Table October 2010 [1 page]

Prosima Trainee Invite- Advanced Pelvic Floor Course with Gynecare Prosima Saturday, October 24, 2009 [1 page]

Reisenauer Summary Positioning Prosima- Ethicon Women's Health & Urology eClinical Compendium- Article Summary [2 pages]

**Testimonial Videos** 

TVT & TVT-O Long Term Studies (94 pages)

Video titled Prosima Shortened Procedure. Hydrodissection and Dissection.

Video: 2010 Prosima Testimonial for NTM

Wound Closure Manual

Zycynski Summary Positioning Prosima- Ethicon Women's Health & Urology eClinical Compendium- Article Summary

### Testimony

Rosenzweig, Bruce, M.D. - 7.14.17 (de bene esse TVT-S deposition)

Rosenzweig, Bruce, M.D. - 7.15.17 (de bene esse TVT-S deposition)

Rosenzweig, Bruce, M.D. - 7.16.17 (de bene esse TVT-S deposition)

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## **Other Materials**

Rosenzweig, Bruce, M.D. - 7.17.17 (de bene esse TVT-S deposition)

## **MDL Wave Cases**

Depositions
Blaivas, Jerry (Edwards TVT-O) - 3.28.2014
Blaivas, Jerry (Farrell Prolift) - 08.13.2015
Blaivas, Jerry (Prolift General Plaintiff Expert) - 03.02.2016
Blaivas, Jerry (TVT General) 9.17.2015
Blaivas, Jerry (TVT General) 9.24.2015
Blaivas, Jerry (TVT-Abbrevo) - 03.06.2016
Blaivas, Jerry (TVT-S & Abbrevo General Plaintiff Expert) - 03.03.2016
Blaivas, Jerry (Wheeler-Graham Plaintiff Expert) - 03.18.2016
Elliott, Daniel (Bellew Prolift) - 9.13.2014
Elliott, Daniel (Gross/Wicker/NJ Prolift) 11.15.12
Elliott, Daniel (Gross/Wicker/NJ Prolift) 11.16.12
Elliott, Daniel (Hammons Prolift) - 11.21.2015
Elliott, Daniel (TVT General) 9.26.2015
Elliott, Daniel (TVT-O General) 3.6.16
Elliott, Daniel (TVT-S General) - 03.06.2016
Garely, Alan D. (General Prolift/Prolift+M) - 04.15.2016
Guelcher, Scott (General) - 03.23.2016
lakovlev, Vladimir, M.D. (TVT General) - 09.11.2015
Margolis, Michael (Carlino TVT) 11.21.2015
Margolis, Michael (Cederberg TVT, TVT-S) - 04.29.2017
Margolis, Michael (Daino Plaintiff Expert) - 03.19.2016
Margolis, Michael (Lewis TVT) 11.25.2013
Mays, Jimmy W., Ph.D. (General Plaintiff Expert) - 03.02.2016 (Blake, Bonnie)
Moore, Robert (TVT-O General) 4.15.16
Ostergard, Donald (General Plaintiff Expert) - 03.09.2016
Priddy, Duane, Ph.D. (General Plaintiff Expert) - 03.08.2016
Reeves, Keith (Hill Plaintiff Expert) - 03.21.2016
Rosenzweig, Bruce (Adkins TVT Secur) - 02.22.2017
Rosenzweig, Bruce (Carlino TVT) 1.13.2016
Rosenzweig, Bruce (Carlino TVT) 1.14.2016
Rosenzweig, Bruce (Carlino TVT) 12.22.2015
Rosenzweig, Bruce (Cavness Prosima) 7.13.2015
Rosenzweig, Bruce (Engleman TVT-S) - 01.17.2017
Rosenzweig, Bruce (Jasso Prosima) - 07.14.2016
Rosenzweig, Bruce (Lewis TVT) 11.04.2013
Rosenzweig, Bruce (McGee TVT Secur) - 02.04.2016
Rosenzweig, Bruce (Perry TVT Abbrevo) 12.15.2014
Rosenzweig, Bruce (Ramirez TVT-O) - 10.11.2014
Rosenzweig, Bruce (Ramirez TVT-O) 3.31.2016
Rosenzweig, Bruce (Susan Smith TVT-O) 8.31.2016 Rosenzweig, Bruce (TVT General) 9.22.2015
Rosenzweig, Bruce (171 General) 9.22.2015  Rosenzweig, Bruce Huskey/Edwards TVT-O) 3.24.2014
Rosenzweig, Bruce, M.D 7.14.17 (de bene esse TVT-S deposition)
Rosenzweig, Bruce, M.D 7.15.17 (de bene esse TVT-S deposition)  Rosenzweig, Bruce, M.D 7.15.17 (de bene esse TVT-S deposition)
Rosenzweig, Bruce, M.D 7.16.17 (de bene esse TVT-S deposition)
Rosenzweig, Bruce, M.D 7.17.17 (de bene esse TVT-S deposition)
mosenzweig, brace, m.b. 7.17.17 (ac bene esse i vi 3 deposition)

## **MDL Wave Cases**

MDL Wave Cases
Shobeiri, Abbas (TVT-O) 2.27.2016
Shull, Robert (Prolift, Prolift+M) - 03.15.2016
Veronikis, Dionysios (Gynemesh PS General) 4.30.2016
Veronikis, Dionysios (TVT General) 4.30.2016
Wilson, Anne (General Plaintiff Expert) - 03.22.2016
Zipper, M.D. Ralph (General)
Zipper, Ralph (General Prosima, Prolift, Prolift+M) 3.20.2016
Expert Reports
Blaivas, Jerry (Prolift General)
Blaivas, Jerry (TVT Abbrevo General) - 02.01.2016
Blaivas, Jerry (TVT General) - 02.01.2016
Blaivas, Jerry (TVT-O General) - 02.01.2016
Blaivas, Jerry (TVT-S General) - 02.01.2016
Blaivas, Jerry (Wave 4 Prolift General) - 01.17.2017
Blaivas, Jerry (Wave 4 TVT-O General) - 01.17.2017
Elliott, Daniel (Prolift General) - Received 05.22.2017
Elliott, Daniel (Supplemental TVT General) - 01.2017
Elliott, Daniel (TVT General) - 02.01.2016
Elliott, Daniel (TVT-O General) - 02.01.2016
Elliott, Daniel (TVT-S General) - 01.25.2016
Elliott, Daniel (Wave 5 TVT-O General) - 05.22.2017
Elliott, Daniel (Wave 5 TVT-S General) - 05.22.2017
Garely, Alan (Prolift +M General) - Received 05.22.2017
Guelcher, Scott (General) - Received 05.05.2016
Guelcher, Scott (Wave 5 General) - Received 05.22.2017
lakovlev, Vladimir (General) - 01.29.2016
lakovlev, Vladimir (Wave 10 General) - 02.20.2019
Jordi, Howard (General) - 02.01.2016
Klinge, Uwe (POP General) - 11.17.2015
Klinge, Uwe (TVT General) - 11.16.2015
Margolis, Michael (TVT General) - 02.01.2016
Margolis, Michael (Wave 5 TVT General) - 05.21.2017
Margolis, Michael (Wave 5 TVT-O General) - 05.21.2017
Mays, Jimmy (General) - 04.29.2016
Mays, Jimmy (Wave 5 General) - 05.22.2017
MDL Wave 9 and 10 Plaintiff General Reports
Michaels, Paul (General) - 07.01.2016
Moore, Robert (TVT-O General)
Muehl, Thomas (POP General) - 11.16.2015
Ostergard, Donald (Prolift, Gynemesh, Prolene General) - 1.31.2016
Ostergard, Donald (Wave 5 Prolift, Gynemesh, Prolene General) - 05.19.2017
Parisian, Suzanne (Prolift +M General) - 01.30.2016
Parisian, Suzanne (TVT-S General) - 01.30.2016
Pence, Peggy (Notice of Adoption of Prior Reports) - 02.01.2016
Pence, Peggy (Prolift General) - 07.17.2014
Pence, Peggy (Prosima General) - 02.01.2016
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#### **MDL Wave Cases**

Pence, Peggy (Supplemental TVT & TVT-O General) - 03.02.2016 Pence, Peggy (TVT General) - 10.14.2013 Pence, Peggy (TVT-O General) - 07.17.2014 Plaintiff expert reports and materials cited in Wave general reports of Rosenzweig, Margolis, Elliott, Blaivas, Veronikis, Moore, Ostergard, Shobeiri, Zipper, Garley and Shull Plaintiffs' Wave general expert reports and materials cited Priddy, Duane (General) - Received 05.05.2016 Raybon, Brian (Prolift +M General) Raybon, Brian (Prolift General) - 01.26.2016 Raybon, Brian (Wave 12 Gynemesh/Prolift General) - 08.19.2019 Rosenzweig, Bruce (Prosima General) - 02.01.2016 Rosenzweig, Bruce (TVT Abbrevo General) - 01.17.2016 Rosenzweig, Bruce (TVT Exact General) - 01.17.2016 Rosenzweig, Bruce (TVT General) - 06.09.2014 Rosenzweig, Bruce (TVT General) - 08.24.2015 Rosenzweig, Bruce (TVT General) - 10.14.2013 Rosenzweig, Bruce (TVT Supplemental General) - 01.06.2017 Rosenzweig, Bruce (TVT, TVT-O Notice of Adoption of Prior Reports) - 12.15.2015 Rosenzweig, Bruce (TVT-O General) - 02.21.2014 Rosenzweig, Bruce (TVT-O General) - 04.24.2015 Rosenzweig, Bruce (Wave 5 Prosima General) - 05.22.2017 Rosenzweig, Bruce (Wave 5 TVT Abbrevo General) - 05.22.2017 Rosenzweig, Bruce (Wave 5 TVT Exact General) - 05.22.2017 Rosenzweig, Bruce (Wave 5 TVT General) - 05.22.2017 Rosenzweig, Bruce (Wave 5 TVT-O General) - 05.22.2017 Rosenzweig, Bruce (Wave 5 TVT-S General) - 05.22.2017 Shobeiri, Abbas (TVT-O General) - 02.01.2016 Shull, Bob (Prolift/Prolift +M General) - 02.01.2016 Veronikis, Dionysios (Gynemesh (and Prolene Soft Mesh) General) Veronikis, Dionysios (TVT General) - 01.25.2016 Wilson, Anne (TVT General) - 01.25.2016 Wilson, Anne (TVT-O General) - Received 05.05.2016 Wilson, Anne (TVT-S General) - 02.01.2016 Zipper, Ralph (Prolift General) - 01.31.2016 Zipper, Ralph (Prosima General) - 02.01.2016

#### **Barbara Smith - Case Specific**

De	positions	
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Clark, Amanda L., MD - 6.16.2021

Elliott, Daniel, MD - 08.31.2019

Elliott, Daniel, MD - 4.10.2021

Ritter, Michelle, MD - 4.23.2021

Smith, Barbara L. - 06.18.2019

Smith, Barbara - 12.15.2016

Wheat, Jeffrey, MD - 06.12.2021

Zenthoefer, Peter MD - 1.31.2017

#### **Expert Reports**

Elliott, Daniel S., MD (Case Specific) - 1.14.2017

Elliott, Daniel S., MD (Supplemental Case Specific) - 5.23.2019

Elliott, Daniel S., MD (Second Supplemental Case Specific) - 6.30.2021

Plaintiff's General Expert Reports

#### **DEFENSE**

Flynn, Brian (Prolift General) - 01.25.2017

Flynn, Brian (TVT-O General) - 02.26.2016

Maclean, Steven (General 8) - 08.13.2018

Pramudji, Christina (Gynemesh PS Prolift Prosima General) - 02.25.2016

Pramudji, Christina (TVT TVT-O General) - 02.26.2016

Stanford, Edwards (POP TVM General) - 03.25.2019

Stanford, Edwards (TVT General) - 06.22.2019

Ulatowski, Timothy (Prolift General) - 02.24.2016

Ulatowski, Timothy (TVT-O General) - 02.24.2016

#### Other

4-17-2006 implant op report

4-17-2006 PID stickers x 2

7-14-2011 #1 explant op report

7-14-2011 pathology report

8-16-2012 #2 explant op report

8-16-2012 pathology report

PFS fed Wave 4

Updated PFS (fed)

#### **Medical Records**

Centers for Medicare and Medicaid Services (Region 10) - Medicare 1-12

Documents produced by all treating physicians

Hindahl, David, Dr. - Medical 1-5

Hindahl, David, Dr. - Medical 757-1312

Hindahl, David, Dr. - Medical 7-756

Kaiser Permanente - Film Inventory 1-1

Kaiser Permanente - Medical 1501-1807

Kaiser Permanente - Medical 1-750

Kaiser Permanente - Medical 1809-1814

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Kaiser Permanente - Medical 2081-2138 Kaiser Permanente - Medical 751-1500 Kaiser Permanente - Pathology 2-2 Kaiser Permanente - Pathology 3-3 Kaiser Permanente - Pathology 3-3 Kaiser Permanente - Pathology Inventory 2-2 Kaiser Sunnybrook Urology - Medical 1501-1588 Kaiser Sunnybrook Urology - Medical 1-750 Kaiser Sunnybrook Urology - Medical 751-1500 Plaintiff Fact Sheet 1-29 Plaintiff Fact Sheet 30-63 Plaintiff Fact Sheet 4-93 Plaintiff Fact Sheet 94-132 Plaintiff Profile Form 1-6 Plaintiff Supplied Records 1658-1815 Plaintiff Supplied Records 1-750 Plaintiff Supplied Records 1816-1832 Plaintiff Supplied Records 1816-1832 Plaintiff Supplied Records 1833-1833 Plaintiff Supplied Records 1834-1869 Plaintiff Supplied Records 1909-1913 Plaintiff Supplied Records 1914-2049 Plaintiff Supplied Records 2050-2052 Plaintiff Supplied Records 751-907 Plaintiff Supplied Records 908-1657 Providence Oregon Regional Lab - Pathology 1-1 Providence Portland Medical Center - Medical 1-10 Ritter, Michelle Lee, MD - Medical 1-11				
Kaiser Permanente - Medical 751-1500 Kaiser Permanente - Pathology 2-2 Kaiser Permanente - Pathology 3-3 Kaiser Permanente - Pathology 3-3 Kaiser Permanente - Pathology Inventory 2-2 Kaiser Sunnybrook Urology - Medical 1501-1588 Kaiser Sunnybrook Urology - Medical 1-750 Kaiser Sunnybrook Urology - Medical 751-1500 Plaintiff Fact Sheet 1-29 Plaintiff Fact Sheet 30-63 Plaintiff Fact Sheet 4-93 Plaintiff Fact Sheet 84-132 Plaintiff Forfile Form 1-6 Plaintiff Frofile Form 7-12 Plaintiff Supplied Records 1658-1815 Plaintiff Supplied Records 1816-1832 Plaintiff Supplied Records 1816-1832 Plaintiff Supplied Records 1833-1833 Plaintiff Supplied Records 1840-1905 Plaintiff Supplied Records 1909-1913 Plaintiff Supplied Records 1914-2049 Plaintiff Supplied Records 2050-2052 Plaintiff Supplied Records 908-1657 Providence Portland Medical Center - Medical 1-10 Ritter, Michelle Lee, MD - Medical 1-11	Kaiser Permanente - Medical 1815-2080			
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Supplemental medical, pharmacy, and employment records for Barbara Smith	Ritter, Michelle Lee, MD - Medical 1-11			
	Supplemental medical, pharmacy, and employment records for Barbara Smith			

Name	Matter ID	Provider	PageRange
Smith, Barbara	106086	Centers for Medicare and Medicaid Services (Region 10)	00001 - 00012
Smith, Barbara	106086	Kaiser Permanente	00001
Smith, Barbara	106086	Kaiser Permanente	00002
Smith, Barbara	106086	Kaiser Permanente	00001
Smith, Barbara	106086	Kaiser Permanente Patient Billing Patient Billing	00001 - 00042
Smith, Barbara	106086	Kaiser Permanente Patient Billing Patient Billing	00043 - 00071
Smith, Barbara	106086	Kaiser Permanente Patient Billing Patient Billing	00072
Smith, Barbara	106086	Kaiser Permanente Release of Information Release of Information	00001 - 00750
Smith, Barbara	106086	Kaiser Permanente Release of Information Release of Information	00751 - 01500
Smith, Barbara	106086	Kaiser Permanente Release of Information Release of Information	01501 - 01807
Smith, Barbara	106086	Kaiser Permanente Release of Information Release of Information	01808
Smith, Barbara	106086	Legacy Health Release of Information Medical Records Department Medical Records Department	00001
Smith, Barbara	106086	Plaintiff Fact Sheet	00001 - 00029
Smith, Barbara	106086	Plaintiff Profile Form	00001 - 00006
Smith, Barbara	106086	Plaintiff Profile Form	00007 - 00012
Smith, Barbara	106086	Plaintiff Supplied Records	00001 - 00750
Smith, Barbara	106086	Plaintiff Supplied Records	00751 - 00907
Smith, Barbara	106086	Plaintiff Supplied Records	00908 - 01657
Smith, Barbara	106086	Plaintiff Supplied Records	01658 - 01815
Smith, Barbara	106086	Plaintiff Supplied Records	01816 - 01832
Smith, Barbara	106086	Plaintiff Supplied Records	01833
Smith, Barbara	106086	Providence Health & Services Medical Records Department Medical Records Department	00011
Smith, Barbara	106086	Providence Oregon Regional Laboratory	00001
Smith, Barbara	106086	Providence Portland Medical Center	00001
Smith, Barbara	106086	Providence Portland Medical Center Medical Records Department Medical Records Department	00001 - 00010
Smith, Barbara	106086	Providence Portland Medical Center Patient Billing Patient Billing	00001

# **Douglas Grier**

# Updated Materials List in Addition to Materials Referenced in Report

**Barbara Smith** 

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#### **Barbara Smith - Case Specific**

Depositions			
Smith, Barbara - 12.15.2016			
Zenthoefer, Peter MD - 1.31.2017			
Expert Reports			
Elliott, Daniel S., MD (Case Specific) - 1.14.2017			
Elliott, Daniel S., MD (Case Specific) - 5.23.2019			
Plaintiff's General Expert Reports			
Other			
4-17-2006 implant op report			
4-17-2006 PID stickers x 2			
7-14-2011 #1 explant op report			
7-14-2011 pathology report			
8-16-2012 #2 explant op report			
8-16-2012 pathology report			
PFS fed Wave 4			
Medical Records			
Centers for Medicare and Medicaid Services (Region 10) - Medicare 1-12			
Documents produced by all treating physicians			
Kaiser Permanente - Medical 1501-1807			
Kaiser Permanente - Medical 1-750			
Kaiser Permanente - Medical 751-1500			
Kaiser Permanente - Pathology Inventory 2-2			
Kaiser Permanente - Film Inventory 1-1			
Plaintiff Fact Sheet 1-29			
Plaintiff Profile Form 1-6			
Plaintiff Profile Form 7-12			
Plaintiff Supplied Records 1658-1815			
Plaintiff Supplied Records 1-750			
Plaintiff Supplied Records 1816-1832			
Plaintiff Supplied Records 751-907			
Plaintiff Supplied Records 908-1657			
Providence Oregon Regional Lab - Pathology 1-1			
Providence Portland Medical Center - Billing 1-1			
Providence Portland Medical Center - Medical 1-10			

Supplemental medical, pharmacy, and employment records for Barbara Smith

# **Douglas Grier**

Supplemental General Materials List in Addition to Materials Referenced in Report

#### Description

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Zullo MA, Plotti F, Calcagno M, et al. One-year follow-up of tension-free vaginal tape (TVT) and Transobturator suburethral tape from inside to outside (TVT-0) for surgical treatment of female stress urinary incontinence: a prospective randomised trial. Eur Urol 2007; 51: 1376-1382; discussion 1383-1384.

Zyczynski H. [Pop 597, 2 yr fu] Sexual Activity and function in women more than 2 years after midurethral sling placement. Am J Obstet Gynecol 2012; 207: 421.e1-6

Zyczynski HM, et al. (Prosima Study investigators) One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device. AJOG 2010; 203: 587.e1-8

Zyczynski HM, et al. [AUA Abs 1354] A new operation for vaginal prolapse repair using mesh and a vaginal support device: 1 year anatomic and functional results of an international multicenter study. J Urol; 181(4), Suppl, April 2009.

### **Document Description [Bates Range]**

000001\_4275674\_d\_Use of Gynemesh PS in Prolapse Surgery Power Point

02.01.2012 Prosima 522 cover letter

02.01.2012 Prosima Postmarket Surveillance Study PS120044; Gynecare Prosima Pelvic Floor Repair Systems

10/12/1990 Letter from FDA re: N16374, Prolene Polypropylene Nonabsorbable Suture

2000 June TVT Surgeons Resource Monograph

2000 TVT Surgeon Monograph

2001 TVT Surgeon's Monograph

2003 Gynemesh PS white paper. Gynemesh PS Early Clinical Experience.

2004 Gynemesh PS Study Poster - AUGS 2004 San Diego. Lucente V, Hale D, Miller D, Madigan J. A Clinical Assessment of Gynemesh PS for the Repair of Pelvic Organ Prolapse.

2005-06 Prof Ed Slides

2006 Mar 3 Flatow memo - CPC-2006-0165 Performance evaluation of TVT PROLENE blue Mesh\_ Elongation Properties of Mechanical Cut verses Laser Cut

2007 Prolift Professional Education Slide Deck

2007 Prolift Surgeon's Resource Monograph

2007 Prolift Surgical Technique Guide

2008 Carey - Vaginal surgery for POP using mesh and a vaginal support device

2008 Prolift Patient Brochure

2009 Zyczynski - AUA Abs 1354 A new operation for vaginal prolapse repair using mesh and a vaginal support device: 1 year anatomic and functional results of an international, multicenter study. J Urol; 181(4) (Suppl), 4.28.2009

2011 Pelvic Organ Prolapse and Stress Urinary Incontinence Patient Counseling Guide

2011 Singh - ICS Abs 575 Anatomic, functional and ultrasound outcomes after vaginal prolapse surgery using non-anchored mesh

2012 Sayer, Hinoul, Gauld (Prosima) - [IUJ] Medium-term clinical outcomes following surgical repair for vaginal prolapse with tension-free mesh and vaginal support device. Int Urogynecol J (2012) 23:487-493

24 Hour Summary of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee Meeting [02.26.2016].

5.15.08 Summary of Safety and Effectiveness - Prolift

6.2.2006 Ethicon Expert Meeting Meshes for Pelvic Floor Repair.

9.22.2011 Letter to surgeons

A Clinical Assessment of Gynemesh PS for the repair of pelvic organ prolapse by V. Lucente, et al.

A Solution-Gynecare TVT Tension-Free Support for Incontinence.

ACOG Surgery for Pelvic Organ Prolapse - FAQ (Frequently Asked Questions).

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Australian Pelvic Floor Discussion

Barber MD, et al. Defining Success After Surgery for Pelvic Organ Prolapse. Obstet Gynecol (2009) 114: 600-609.

Benefit Risk Profile of Transvaginal Mesh Products Used for the Treatment of Pelvic Organ Prolapse signed by Piet Hinoul

Benefit Risk Profile of Transvaginal Mesh Products Used for the Treatment of Pelvic Organ Prolapse signed by Piet Hinoul dated 6/21/2012

Biocompatibility Risk Assessment Report for GYNECARE GYNEMESH PS PROLENE - Appendix 1: Tabular Summaries....nrl

Biocompatibility Risk Assessment Report for GYNECARE GYNEMESH PS PROLENE - Appendix 2: Brief CV's... (2).nrl

Biocompatibility Risk Assessment Report for GYNECARE GYNEMESH PS PROLENE... (1).nrl

Boukerrou, M., et al. "Tissue resistance of the tension-free procedure: What about healing?" Int Urogynecol J (2008) 19:397-400.

Brigette Fatton Powerpoint Presentation entitled "Complications in Pelvic Floor Dysfunction Surgery: evaluation and management.

Chevron Phillips MSDS (Exhibit T, No. 3137 - 8.9.2013)

Classification Website Intro "An International Urogynecological Association (IUGA/Internation Continence Society (ICS) Joint Terminology and Classification of the Complications Related Directly to the Insertionm of Prostheses (Meshes, Implants, Tapes) & Grafts in Female Pelvic Floor Surgery."

Clinical Evaluation Report - Gynecare Prolift signed by P. Hinoul on 04.26.2013

Clinical Evaluation Report, Gynecare TVT Tension-free Vaginal Tape / Tension-free Vaginal Tape Accessory Abdominal Guide [ETH.MESH.4384126-65]

Clinical Expert Report [ETH.MESH.1784823-28]

Clinical Expert Report [ETH.MESH.222899-909]

Clinical Expert Report Gynecare Prolift +M™ Pelvic Floor Repair System signed by Piet Hinoul dated 9/25/2012 [ETH.MESH.08315779-810]

Corporate Product Characterization Plan, TVT-Laser Cut Mesh. Dated 02/06/2006.

Correspondence between Morgan Liscinsky of FDA & Bloomberg re: Johnson & Johnson Vaginal Mesh Implant.

D00001256-2005 Prolift Ed Gynecare Prolift Pelvic Floor Repair

D00001260-2007 and 2008 Prolift and M Prof Ed

Dear Surgeon Letter from Piet Hinoul and Aaron Kirkemo.

Declaration of Reynaldo Librojo in Support of Motion for Summary

Declaration of Thomas A. Barbolt, Ph.D., DABT, 1981-2011 in Support of Motion for Summary Judgement

Defense 1584 - One Year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device

Defense 2 - Clinical Assessment of Gynemesh PS for the Repair of Pelvic Organ Prolapse

Demonstrative - Ethicon Powerpoint - Almost uniformly, physicians did not express a preference for company name (Engleman trial exhibit)

Demonstrative - Ethicon powerpoint - Next generation slings - evaluating opportunities, considering risks (Engleman trial exhibit)

Demonstrative - Powerpoint - Warning regarding FBR inflammatory response (pgs 18, 22-27)(Engleman trial exhibit)

DEPO.ETH.MESH.00004755 - Guidoin Explant

Document entitled "Delay in Prosima Activities"

Document entitled "Pelvic Floor Repair. Extended Review of Medical Literature."

DX23600-R.1-3 - Prolene Resin Manufacturing Specifications 1.23.03

Email dated 1/17/2010 from Dr. Piet Hinoul to Dr. David Robinson, et al. Re: +M relaxation

[ETH.MESH.01785259-60]

Email dated 1/22/2010 from Scott Jones to Kevin Frost and Tom Affeld re: Summit Agenda/Moderator; cc: Matt Henderson, et al. [ETH.MESH.00817181]

Email dated 6/8/2012 from Matt Henderson to Tim Schmid re: 522 Communication Recap

[ETH.MESH.04568519]

Email dated 9/3/2009 from Piet Hinoul to David Robinson, et al. re: Prosima Take Away Messages; cc: Peter Meier [ETH.MESH.01237077-79]

Email from Arnaud re: Transient Leg Pain with Mulberry [ETH.MESH.3911390-1]

Email from Dan Smith re: Draft report translated by "Babel fish" http://babelfish.altavista.com/tr [ETH.MESH.865069-72]

Email from Dan Smith re: NG TVT-O NDP - Outcomes from Kickoff Meeting with Pr. De Leval & Dr. Waltregny [ETH.MESH.2293715-6]

Email from Frost to Globerman, et al. re: prosima usage northeast [ETH.MESH.11538048-49]

Email from Frost to Affeld, et al. re: Sales Rep Training on Prosima 5/18 [ETH.MESH.03895925-26]

Email from Hinoul re: South Africa, TVTO sheaths getting stuck upon removal [ETH.MESH.1210987-95]

Email From Lewis to Mahar, et al. re: How did Dr. Grier's Prosima cases go? [ETH.MESH.00127125-26]

Email from O'Bryan re: GYNECARE TVT Obturator System - FDA [ETH.MESH.6882641-2]

Email from O'Bryan re: ifu [ETH.MESH.3364663-66]

Email from Scott Jones to DL-Ethusso dated 12/15/2009 re: PAGS Leads [ETH.MESH.00662233]

Email from Seppa re: Performance Evaluation of TVT Secur PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920) (4.25.2005)

Email from Seppa re: Performance Evaluation of TVT U PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920) Version 2

Email from Seppa re: Performance Evaluation of TVT U PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920) Version 2 (5.4.2005)

Email from Shalot Armstrong dated 9.1.10 [ETH.MESH.07453752-57]

Email from Shalot Armstrong dated 9.1.10 [ETH.MESH.08918949-52]

Email from Tim Schmid to Chuck Austin dated 6/8/12 re: Prolift +M withdrawal notice [ETH.MESH.04568717-18]

Email from Weisberg re: IFU update [ETH.MESH.3365250-1]

Email from Weisberg re: Mulberry [ETH.MESH.6886410-11]

Email re: 60% Success [ETH.MESH.01776504-10]

Email re: 69% Success [ETH.MESH.00547500-501]

Email re: Alerte TVT Abbrevo (April 3, 2012) [ETH.MESH.03941617-18]

Email re: Alerte TVT Abbrevo (May 10, 2012) [ETH.MESH.05998835-36]

Email re: Faculty & Customer Call Post-FDA Panel Mtg on 9/12 [ETH.MESH.04543334]

Email re: IFU errors [ETH.MESH.02229013]

Email re: Important Laser cut mesh update [ETH.MESH.1809056-58]

Email re: Laser Cut TVT [ETH.MESH.6859834-35]

Email re: Meeting Minutes from April 18 2012 meeting w FDA [ETH.MESH.04476274-75]

Email re: Mesh Fraying Dr. EBERHARD letter [ETH.MESH.7692905-7]

Email re: No RCT for Prosima [ETH.MESH.00592585-87]

Email re: OR Agenda Tunn [ETH.MESH.3922926-28]

Email re: Overstating Success - Less Misleading [ETH.MESH.00594266]

Email re: Performance Evaluation of TVT Prolene Blue Mesh [ETH.MESH.6696411-19]

Email re: Piet explaining why no Ultrapro in Prosima [ETH.MESH.01237077-79]

Email re: Piet explaining why Prosima uses a VSD [ETH.MESH.00580588-89]

Email re: Piet explains PS in Prosima [ETH.MESH.00580711-13]

Email re: Piet following 2011 Ad Com [ETH.MESH.04568448]

Email re: Piet re Problem with posterior inserter [ETH.MESH.02579701-06]

Email re: Piet's response to 522 FDA refusal [ETH.MESH.05987605-06]

Email re: Piet's response to 522 FDA refusal clean [ETH.MESH.04548975]

Email re: Piet's takeaways from 2011 FDA meeting [ETH.MESH.04556236]

Email re: Prof. de Leval - TVT Abbrevo (April 2, 2012) [ETH.MESH.04938298-99]

Email re: Prosima Jan 2007 Updated [ETH.MESH.00455676-77]

Email re: Smelly VSDs [ETH.MESH.00591563-65]

Email re: Stop communicating over email [ETH.MESH.00594455]

Email re: TVT Laser Cut Mesh [ETH.MESH.525573]

Email re: TVT Laser Mesh info [ETH.MESH.442825-26]

Email re: TVT Meeting with Agency [ETH.MESH.524746-48]

E-mail string dated 1/21/2010, top one from Piet Hinoul to Clifford Volpe and David Robinson re: dimensions of the PROSIMA implant [ETH.MESH.00851319-21]

E-mail string dated 11/3/2010 re: neo clinical trial. Piet Hinoul: "Each individual study does not contribute to the success of those products [ETH.MESH.00856579-82]

Email string dated 3/25/2010, top one from Piet Hinoul to Paan Hermansson re: key message for Prosima launch [ETH.MESH.00580588-89]

Email string dated 5/12/2011, top one from Kevin Frost to Benjamin Bouterie re: Dr. Bedestani; cc: Stacy Hoffman [ETH.MESH.03466382-83]

Email string re - Revised write up of the DeLeval and Waltregny visit

Email string re: Ultrapro vs Prolene Soft Mesh

Email string, top one from Gary Pruden to David Robinson, et al. re: article entitled: Vaginal repair with mesh no better than colporrhapy for pelvic organ prolapse.

ETH.MESH.00000172 8/25/11 Email from Marie Hobson to Kevin Frost attaching registration list for call

ETH.MESH.00000173 - 8/25/11 Registration list for 8/25/11 call

ETH.MESH.00001314 - Gynecare Prolift Pelvic Floor Repair System

ETH.MESH.00001595-1606 - Reisenauer C. Anatomical conditions for pelvic floor reconstruction with polypropylene implant and its application for the treatment of vaginal prolapse. Eur J Obstet Gynecol Reprod Biol 2006

ETH.MESH.00003895 - Continence Health and Pelvic Floor Advisory Board Opening Comments for Renee

ETH.MESH.00012009-089 - Clinical Study Report: Clinical assessment of feasibility, complications and effectiveness at twelve months, three years and five years of the TVM technique for genital prolapse.

ETH.MESH.00012009-74 - Cosson M. Clinical assessment of feasibility, complications and effectiveness at twelve months, three years and five years of the TVM technique for genital prolapse(French 1 year CSR)

ETH.MESH.00012090-163 - Robinson D. Clinical assessment of the TVM technique for treatment of genital prolapse. Final Report of 12-month evaluation. (US 1 year CSR)

ETH.MESH.00013529-534 - Prolift+M IFU

ETH.MESH.00016032-039 - Kohli, N. Augmenting pelvic floor repairs. 2006 Supplement to OBG Management

ETH.MESH.00017362-368 - Elmer C, et al. Histological inflammatory response to transvaginal polypropylene mesh for pelvic reconstructive surgery. J Urol (2009); 181(3): 1189-95.

ETH.MESH.00017553-560 - Tunuguntla, H. Female Sexual Dysfunction Following Vaginal Surgery: A Review. Journal of Urology 2006; 175: 439-446

ETH.MESH.00018344-479 - Gynemesh PS Prof Ed Slide Deck 2007 000001 168547 d

ETH.MESH.00018382 - 2007 Powerpoint GYNECARE GYNEMESH\* PS Nonabsorbable PROLENE\* Soft Mesh in the Treatment of Pelvic Organ Prolapse\_DX24191

ETH.MESH.00018382 - Powerpoint: Gynecare Gynemesh PS Nonabsorable Prolene Soft Mesh in the Treatment of Pelvic Organ Prolapse

ETH.MESH.00019117-121 - Prosima Launch Memo with Prepceptor Info from Hilaire

ETH.MESH.00019117-121 Letter from Scott H. Jones to Price St. Hilaire re: Prosima US Launch Plan; cc: Renee Selman, et al.

ETH.MESH.00020763

ETH.MESH.00020764

ETH.MESH.00028555-556 (Adkins Trial Exhibit P2669)

ETH.MESH.00031323 - Memo to Customer from Sean M. OBryan

ETH.MESH.00031324-325 - Letter to Gregory Jones from Celia M. Witten

ETH.MESH.00064002-004 Email string, top one from Judith Gauld to Scott Jones re: US preceptors for Prosima.

ETH.MESH.00064054 - Gynecare Prosima ™ Pelvic Floor Repair System - Global Launch Strategy

ETH.MESH.00064138-139 Document entitled "PROSIMA Critical Success Factors."

ETH.MESH.00071755 - Prosima - Apical Support Learning Guide

ETH.MESH.00071794 - Email re: TVT IFUs on tape extrusion, exposure and erosion

ETH.MESH.00076167 - Letter from Bryan Lisa to Dan Smith re: Prosima Product Release Authorization; cc: Stephanie Kute, Jennifer Paine.

ETH.MESH.00076167 - Prosima Product Release Authorization (July 2007)

ETH.MESH.00076710-790 Clinical Study Report. Evaluation of Prosima for Pelvic Organ Prolapse. Protocol Number: 300-06-005. "A Prospective, Multi-centre Study to Evaluate the Clinical Performance of Gynecare Prosima Pelvic Floor Repair System as a Procedure for Pelvic Organ Prolapse."

ETH.MESH.00077073-093

ETH.MESH.00077094-111

ETH.MESH.00077395

ETH.MESH.00077739 - Prosima Story

ETH.MESH.00078114-115 - Memo to Prosima Regulatory File. Minutes from Teleconference with FDA for Prosima 510(k).

ETH.MESH.00082651-654 Email string, top one from Marcus Carey to J. Meek, D. Robinson, P. Hinoul, et al. re: Technical feedback on Prosima.

ETH.MESH.00083812-814

ETH.MESH.00086463-465 E-mail from Piet Hinoul to Zeb Viana, et al. regarding TR: PROSIMA TAKE AWAY MESSAGES; cc: Bart Pattyson, et al.

ETH.MESH.00093526-544

ETH.MESH.00093991

ETH.MESH.00108120-121 Email string, top one from Douglas Grier to Lissette Caro-Rosado, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattyson.

ETH.MESH.00125373 - Email string, top one from Tom Eagan to Erin Haggerty re: Dr. Sepulveda.

# Case 3:20-cv-00851-MO Document 249-6 Filed 06/02/22 Page 214 of 259 Douglas Grier Materials List

### **Production Materials**

ETH.MESH.00126755-757 - Email string, top one from M. Yale to J. Paine, et al. re: Draft FDA response on
Prolift+M for input
ETH.MESH.00127103 - Email from Greg prine to Scott Jones, Jonathan Meek re: Prosima Road Show; cc: Lesley
Fronio and Kevin Mahar.
ETH.MESH.00129102 Suggested Remarks - Incontinence and Pelvic Floor Summit What a Difference a Decade
Makes
ETH.MESH.00131058-095
ETH.MESH.00131149-151 Email string, top one from Stephanie Grupe to Kevin Mahar re: Prosima Global Launch
Team.
ETH.MESH.00134794-795 - Jason Hernandez email to Nicholas Antoun et al dated 02.27.2009 attaching TVT
World Board meeting presentation (Engleman/Adkins Trial Exhibit P0086)
ETH.MESH.00142622-624
ETH.MESH.00143784-785
ETH.MESH.00144210
ETH.MESH.00144211
ETH.MESH.00144270-278
ETH.MESH.00144449 - Letter from David Robinson re: decision to delay preceptor training activities for Prosima
(not signed).
ETH.MESH.00144721-723
ETH.MESH.00145547-548
ETH.MESH.00145551
ETH.MESH.00145555
ETH.MESH.00147320-325
ETH.MESH.00147904
ETH.MESH.00148901-902
ETH.MESH.00153967 (Adkins Trial Exhibit P0127)
ETH.MESH.00155903-905
ETH.MESH.00155903-906
ETH.MESH.00155906
ETH.MESH.00155975
ETH.MESH.00156178-181
ETH.MESH.00156855-856
ETH.MESH.00156906-908
ETH.MESH.00156909-952
ETH.MESH.00156954-955
ETH.MESH.00158065-067
ETH.MESH.00158083-084
ETH.MESH.00159266-369 - Gynemesh PS, Prolene Soft Mesh in the treatment of POP – Pelvic Floor Surgery and
Anatomic Dissection Lab
ETH.MESH.00159410-411
ETH.MESH.00159432-433
ETH.MESH.00159434-465
ETH.MESH.00159884-986
ETH.MESH.00160615-625
ETH.MESH.00166552
ETH.MESH.00166553-555
ETH.MESH.00167104-110 - 2006 Apr 19 - Laser Cut Mesh for Gynecare TVT- CER Laser Cut Mesh

ETH.MESH.00167684-685
ETH.MESH.00169300-303
ETH.MESH.00220335-336 - 12.2.1999 Memo re: Biocompatibility Risk Assessment for Soft Prolene Mesh.
ETH.MESH.00262015-016 - Dan Smith Email Plaintiffs Exhibit 2067
ETH.MESH.00271215-216 - Email from J. Meek to multiple recipients e: Pre-Reading for Prolift+M: Internal Use
Only. Not Copy Reviewed or For Distribution
ETH.MESH.00273967 - Email from Clifford Volpe to Scott Jones re: slides for Pelvic Floor Summit.; Powerpoint:
R&D Perspective - The Journey from Prolift to Prolift +M.
ETH.MESH.00274015 - Krofta Presentation - One year prospective follow-up of the TVT-S Procedure for
treatment of stress urinary incontinence (Engleman Trial Exhibit P0238)
ETH.MESH.00281482-484 - Aaron Kirkemo email to Harel Gadot, et al., re Prosima feedback (Engleman Trial
Exhibit P0241)
ETH.MESH.00295355
ETH.MESH.00303310-313 Memo from Dan Lamont to Gynecare Prosima Risk Management Report (RMR-0000029) re: Pelvic Floor Product(s) Complaint Review for Gyneacre Prosima Risk Management. (March 2007)
ETH.MESH.00308094 (2629 2006-07-12) - 2006 TVT-Secur
ETH.MESH.00310205 - Product Quality Issue re: Prosima signed by Mark Yale.
ETH.MESH.00310206 - Letter from David Robinson re: decision to delay preceptor training activities for Prosima
(not signed).
ETH.MESH.00316849-850
ETH.MESH.00318930 - (Draft) Letter from David Robinson re: delay in preceptor training activities for Prosima.
ETH.MESH.00318934 - Document entitled " Delay in Prosima Activities."
ETH.MESH.00324109 - Carolyn Brennan email to Mark Yale dated 11.02.2006 re TVT-S difficulties with insertion of device (Engleman/Adkins Trial Exhibit P0274)
ETH.MESH.00326842-846 - Catherine Beath email to Sheri McCoy and Renee Selman dated 11.05.2007 re
urgent meeting with Australian to discuss TVT Secur performance - includes email from Aran Maree
dated 11/2/2007 re Australian launch of TVT S (Engleman/Adkins Trial Exhibit P0286)
ETH.MESH.00326911 - Ethicon Delayed Prosima Launch by Two Years
ETH.MESH.00327060-063 - Robinson email (Dr. Aran Maree) chain dated 11.12.2007 re Dr. Frazier's (Australia)
opinions re TVT-S (Engleman/Adkins Trial Exhibit P0290)
ETH.MESH.00328895-901 - David Robinson email to Mark Yale and Daniel Lamont dated 03.03.2008 re quality
issue with a batch of gynemesh (Engleman/Adkins Trial Exhibit P0292)
ETH.MESH.00329474-509 Project Mint Design Review
ETH.MESH.00335084-085 Email from Daniel Lamont to Sungyoon Rha, et al. re: Mint Functional Strategies.
ETH.MESH.00349226-237 - May 26, 2000 Ethicon Memo to P. Cecchini RE: Review of Biocompatibility Data on
the Tension Free Vaginal Tape (TVT) System for Compliance to FDA G-95/ ISO 10993/ EN 30993
ETH.MESH.00349228 - Cytotoxicity Risk Assessment for the TVT (Ulmsten) Device
ETH.MESH.00352889-909
ETH.MESH.00353020-037
ETH.MESH.00354732

ETH.MESH.00365412-414 - June 14, 2007 Memo RE: ADDENDUM: Post - Launch Complaint Review for the PROLIFT\* Pelvic Floor Repair System

ETH.MESH.00365960-965 - Gynecare TVT Secur System Procedural Pearls & Frequently Asked Questions.

ETH.MESH.00369995

ETH.MESH.00369999 (2008-135) - 2008 TVT-Secur

ETH.MESH.00370315 - Prosima Training Deck 1

ETH.MESH.00370421

ETH.MESH.00371595-903 - Prosima 510K and Clearance letter

ETH.MESH.00372564-568

ETH.MESH.00372664-671 - Letter from B. Lisa to J. Dang re: K071512 S04. (02.21.2008)

ETH.MESH.00373310-388 - Gynecare TVT Tension-Free Support for Incontinence: General Profession Education Deck.

ETH.MESH.00393045-46 - TVT-O Procedural Steps

ETH.MESH.00394849 - Gynemesh PS Panel Powerpoint - Drs. Robinson, Miller, Winkler, England

ETH.MESH.00395374-380 - Scientific Advisory Panel on Pelvic Floor Repair Preliminary Minutes Chicago, IL, June 22, 2001

ETH.MESH.00397327

ETH.MESH.00397674

ETH.MESH.00405513-514

ETH.MESH.00409158 - (Official) Letter from David Robinson re: delay in preceptor training activities for Prosima.

ETH.MESH.00418855-856 Email string, top one from Andrew Meek to Jonathan Fernandez, et al. re: Prosima Preceptor Recommendation Form; cc: Kevin Frost, et al.

ETH.MESH.00424374-375 Email string, top one from Jonanthan Fernandez ro Rhonda Peebles re: remaining 2010 labs; cc: Robert Zipfel.

ETH.MESH.00426441 - Email from Kevin Frost to Robert Zipfel, et al. re: Prosima 2-year slide deck; cc: Paul Parisi.

ETH.MESH.00442129

ETH.MESH.00455676-677 Email from Allison London Brown to Ophelie Berthier, et al. re: Prosima Jan 2007 update; cc: Bob Roda, et al.

ETH.MESH.00461576 - 10.23.2006 letter to EWHU field sales force

ETH.MESH.00467320 - Email string, top one from Andrew Meek to Bart Pattyson, Paul Parisi re: November Lab.

ETH.MESH.00484929

ETH.MESH.00495796-798 Email string, top one from Jennifer Paradise to Melissa Doyle, et al. re: Prof Ed through Tele-Mentoring; cc: Paul Parisi, et al.

ETH.MESH.00510562-563 Email string, top one from Kevin Frost to DL-ETHUSSO EWHU DMs, et al. re: 1st Prosima Virtual Round Table Tomorrow; cc: Matt Henderson, et al.

ETH.MESH.00516424-427

ETH.MESH.00520649-722 - 2006 US TVM 12 Month Clinical Report

ETH.MESH.00523617 (2007-4144) - 2007 TVT-Secur Critical Steps

ETH.MESH.00523942 - Waltregny 2005 ICS Presentation

ETH.MESH.00526473-74 - Allison Brown Email re-Laser-cut Mesh

ETH.MESH.00541379-80 - Mesh Fraying for TVT Devices

ETH.MESH.00541391

ETH.MESH.00541708-709 Document entitled "Notes from Competitive Ad Board."

ETH.MESH.00541873 - Chart listing Proposed Lab Scheduling for August 4th.

ETH.MESH.00541876-878 Email string, top one from Bart Pattyson to David Robinson, et al. re: ICS/IUGA Cadaver Lab - Monday Aug 23.

ETH.MESH.00542347-348 Calendar appointment re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones and Schlafstein.; created by Robert Zipfel.

ETH.MESH.00542463 - Powerpoint: Gynecare Prosima ™ Pelvic Floor Repair System: 2-Year Clinical Data

ETH.MESH.00547021 - Ethicon Women's Health & Urology "Welcome Letter" to the EWH&U Pelvic Floor Repair Advisory Board Meeting.

ETH.MESH.00547036-037 Email string, top one from Bart Pattyson to Jaime Sepulveda, et al re: Prosima (&Elevate) Advisory Board - Jan 8th - Baltimore; cc: Piet Hinoul, et al.

ETH.MESH.00547500-001 - P. Hinoul email 11.2009

ETH.MESH.00573815 - Powerpoint: Two Year Clinical Outcomes after Prolapse Surgery with Non-Anchored Mesh & Vaginal Support Device (Gynecare Prosima\* Pelvic Floor Repair System) June 2010.

ETH.MESH.00573860-878 (Draft) Sayer, T., et al. "Medium-term Clinical Outcomes Following Surgical Repair for Vaginal Prolpase with Tension-free Mesh and Vaginal Support Device."

ETH.MESH.00575257 - Abbrevo laser cut vs. mechanically cut - notes from meeting with de leval - inappropriate

ETH.MESH.00575270-273 - Jean de Leval Email Re: DSCN3332.JPG May 30, 2009

ETH.MESH.00575580 to ETH.MESH.00575581 Email string, top one from Jonathan Meek to Piet Hinoul, Colin Urquhart and Judi Gauld re: Prosima anterior compartment result.

ETH.MESH.00575634 to ETH.MESH.00575635 ICS 2009 Abstract Form. "Surgery for Pelvic Organ Prolapse Using Mesh Implants and a Vaginal Support Device: Analysis of Anatomic, Functional and Performance Outcomes from an International, Multicentre Study."

ETH.MESH.00575818-820 - PX0198 - Piet email re Prolift

ETH.MESH.00578081 to ETH.MESH.00578083 Email string, top one from Piet Hinoul to Paan Hermansson re: Prosima Post launch communication.

ETH.MESH.00578550 to ETH.MESH.00578550 (Draft) Sayer, T., et al. "Two Year Clinical Outcomes after Prolapse Surgery with Non-Anchored Mesh and Vaginal Support Device."

ETH.MESH.00578621 - Dr. Piet Hinoul's TVT Secur Literature Analysis; TVT Secur CER 2013

ETH.MESH.00579296 to ETH.MESH.00579296 Powerpoint: Anatomic and Functional Outcomes of 2 Pelvic Floor Repair Systems Studied in Moderate and Severe Prolpase Patients.

ETH.MESH.00580588 to ETH.MESH.00580589 Email string, top one from Piet Hinoul to Paan Hermansson re: key message for Prosima launch

ETH.MESH.00584811-13 - Email string re-Ultrasonic Slitting of Prolene Mesh for TVT

ETH.MESH.00584846-847 - (05.10.2004) Email string, top one from Gene Kammerer to Mora Melican, et al. re: Mesh for TVM.

ETH.MESH.00590896-897 - Piet Hinoul Email 3.11.09

ETH.MESH.00592224 to ETH.MESH.00592229 E-mail chain from Jonathan Meek to otehrs in regards to Technical Feedback on Prosima

ETH.MESH.00594266 - P. Hinoul email to Affeld 11.2009 re success rates

ETH.MESH.00594528 Email from Aaron Kirkemo to Piet Hinoul, David Robinson and Judi Gauld re: Prosima commerical claims of 92.3% above the hymen.

ETH.MESH.00595468 to ETH.MESH.00595470 Goldman, H., FitzGerald, M. "Opposing Views: Transvaginal Mesh for Cystocele Repair," J Urol (2010) 183:430-432.

ETH.MESH.00595889 to ETH.MESH.00595890 Email string, top one from Kevin Frost to Aaron Kirkemo re:

Prosima presentation; cc: Tom Affeld.

ETH.MESH.00604183 to ETH.MESH.00604186 Email string, top one from Piet Hinoul to Judi Gauld and Colin

Urguhart re: PISQ, and score when unable to have sex.

ETH.MESH.00631782 to ETH.MESH.00631784 FDA Letter re: K063562 Gynecare Prosima

ETH.MESH.00637343 - 2004 ETHICON Product Development Process - Gynemesh PS

ETH.MESH.00642325-331 (Adkins Trial Exhibit P0429)

ETH.MESH.00658177-198 - Surgeons Resource Monograph

ETH.MESH.00658421-29

ETH.MESH.00662233-234 - DX24786 - Zyczynski PAGS Convention

ETH.MESH.00679637 to ETH.MESH.00679640 Email string, top one from Zenobia Walji to Ron Naughton, et al.

re: Prolene Soft Mesh '05 proposed pricing; cc: Kevin Maher, et al.

ETH.MESH.00687819-22 - Email string re-Laser cut mesh

ETH.MESH.00747864-874 - Gynemesh PS DDSA (rev. 2 - Feb. 2005)

ETH.MESH.00759327-335 Document entitled "Experience what's new in incontinence and pelvic floor repair."

2010 ICS IUGA Executive Agenda

ETH.MESH.00776993-7000 - Prosima Sales Aid

ETH.MESH.00791497 - Email re Prosima Brochure and DVD

ETH.MESH.00791766 - TVT-Abbrevo Physician Survey Results (January 20, 2011)

ETH.MESH.00800521 to ETH.MESH.00800522 Email string, top one from Kenneth Pagel to Melissa Doyle re: presentation access.

ETH.MESH.00806974 to ETH.MESH.00806975 Email from Lissette Caro-Rosado to Jaime Sepulveda, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattyson, et al.

ETH.MESH.00807570 to ETH.MESH.00807570 Revised Chart listing Proposed Lab Schedule

ETH.MESH.00807772 to ETH.MESH.00807774 Email String, top one from Bart Pattyson to Hugo Ye re: ICS-IUGA - Cadaver Lab & Ask the Expert Update; cc: Ping Li, et al.

ETH.MESH.00807972 to ETH.MESH.00807973 Email string, top one from Bart Pattyson to Tommaso Santini, et al. re: US Surgeon; cc: Tom Affeld.

ETH.MESH.00808121 to ETH.MESH.00808122 Email from bart Pattyson to Jaime Sepulveda et al. re: Prosima (&Elevate) Advisory Board - Jan 8th - Baltimore; cc: Piet Hinoul.

ETH.MESH.00817181 - Email from Scott Jones to Kevin Frost and Tom Affeld re: Summit Agenda/Moderator; cc: Matt Henderson, et al.

ETH.MESH.00820634 - Invitation to participate in Gynecare Prosima Virtual Round Table

ETH.MESH.00832749 to ETH.MESH.00832754 Risk Management Report: Prosima Pelvic Floor Repair Kit

ETH.MESH.00833948 to ETH.MESH.00833949 Email from David Robinson to Jessica Shen re: Prosima Study.

ETH.MESH.00834910 to ETH.MESH.00834911 Email string , top one from David Robinson to Price St. Hilaire, et al. re: Prosima Strategic Council; cc: Kevin Mahar.

ETH.MESH.00840886 to ETH.MESH.00840887 Calendar appointment re: Updated: TVT Secur Preceptor Roundtable Forum; created by Dharini Amin.

ETH.MESH.00843043 - Email from David Robinson to Jacqutin Bernard, Judith Gauld and Jonathan Meek re: cancellation of scheduled Prosima training.

ETH.MESH.00849014-9017

ETH.MESH.00850335-336 Email string, top one from David Robinson to Stephanie Kute, Patrice Napoda re: Prosima FDA Review and IFU; cc: Price St. Hilaire, Dan Smith.

ETH.MESH.00851319-321 - Email string, top one from Piet Hinoul to Clifford Volpe and David Robinson re dimensions of the PROSIMA implant

ETH.MESH.00857821 - Top Ten Reason to pursue Gynecare TVT Obturator System

ETH.MESH.00858080-081 - Perry Trial - Plaintiff's Exhibit 2313

ETH.MESH.00858096-97 - Gynecare R&D Monthly Update - May

ETH.MESH.00858175-176 - Mulberry Weekly Meeting MINUTES for 6.3.03

ETH.MESH.00858252-253 - 2004 Memo from London Brown to Dan Smith re Mechanical Cut vs. Laser Cut Mesh Rationale (Adkins Trial Exhibit P0542)

ETH.MESH.00863391 - T-366 - Dan Smith email - particle loss

ETH.MESH.00870466-476 - (06.02.2006) Ethicon Expert Meeting: Meshes for Pelvic Floor Repair.

ETH.MESH.00874445 TVT-S Quality Board powerpoint (Engleman Trial Exhibit P0581)

ETH.MESH.00895089 to ETH.MESH.00895091 Email string, top one from Kevin Frost to Vincenza Zaddem re: Prosima in R&D Study.

ETH.MESH.00916799 - Project MINT Charter Review

ETH.MESH.00921692 to ETH.MESH.00921694 Email string, top one from Tom Affeld to Scott Jones, et al. re: NEO #2, 3, 4 Lab Nominations; cc: Vincenza Zaddem.

ETH.MESH.00922443-446 - Email string, top one from P. St. Hilaire to B. Lisa, et al. re: Bidirectional elasticity statement

ETH.MESH.00925065 to ETH.MESH.00925067 Email string, top one from Joshua Samon to Vincenza Zaddem re: Mint Value Proposition; cc: Duan Broughton.

ETH.MESH.00991195-257

ETH.MESH.00993273 - 2006 (2091 2006-02-01) TVT-O Summit Presentation by Raders and Lucente

ETH.MESH.00993273 - TVT Obturator Anatomic Considerations Clinical Update: Special Considerations, Complications.

ETH.MESH.00997751 - TVT Secur CER 2005 Eth.Mesh.00997751

ETH.MESH.01000731-735 - David Robinson email to Axel Arnaud and Dan Smith dated 12.19.2006 re TVT-S Cookooks (Engleman/Adkins Trial Exhibit P0619)

ETH.MESH.01075187-215

ETH.MESH.01128679-98 (TVTS007) - 2007 TVT-Secur Procedural Steps

ETH.MESH.01130563-64

ETH.MESH.01130566-68

ETH.MESH.01130567

ETH.MESH.01136239-240 Email string, top one from Lissette Caro-Rosado to Ad Board Members re: EWH&U Pelvic Floor Repair Ad Board 1-8-11; cc: Tom Affeld, et al.

ETH.MESH.01154031-037 - Clinical Expert Report - Gynemesh Prolene Soft

ETH.MESH.01189392 - Summary of sheep and human cadaver labs for development of the GYNECARE TVT SECUR System

ETH.MESH.01189423 - TVT Secur CER 2006

ETH.MESH.01198058 - (Draft) Zyczynski, H., et al. "One year clinical outcomes after prolapse surgery with non-anchored mesh and vaginal support device."

ETH.MESH.01200286 - Powerpoint: Gynecare Prosima: Overview.

ETH.MESH.01201973 - Propsed Lab Schedule (2nd Revision)

ETH.MESH.01202189 - Stale Kvitle Email regarding Mini Me follow up from our visit May 20, 2009

ETH.MESH.01202190-191 - David Waltregny Email Re: Mini Me follow up from our visit May 21, 2009

ETH.MESH.01203957-97 - The future of surgical meshes-the industry's perspective

ETH.MESH.01212972 - Hinoul presentation Incontinence Overview

ETH.MESH.01219542-48 - Review of Surgeon Responses of VOC Questionnaire

ETH.MESH.01220135-45 - Email string re-New Standards for Urethral Slings

ETH.MESH.01222075-79 - TVT Laser Cut Elongation Testing

ETH.MESH.01228079-84 - Nilsson Podcast Transcript

ETH.MESH.01237077-079 Email from Piet Hinoul to David Robinson, et al. re: Prosima Take Away Messages; cc: Peter Meier.

ETH.MESH.01238454-456 - Email string re-TVTO length

ETH.MESH.01244824-826 Email string, top one from Aaron Kirkemo to Cyrus Guidry re: response letter to editor, Lewis Wall.

ETH.MESH.01261962 (2005-1819) - TVT-O Summit by Raders, Rogers, Lucente

ETH.MESH.01264260 - Prolift +M Piet Hinoul Pelvic Floor Meeting Nderland Utrecht, May 7, 2009

ETH.MESH.01271289-301 - TVT with Abdominal Guides Early Clinical Experience

ETH.MESH.01274741-743 - Use of UltraPro Mesh for Pelvic Organ Prolapse (POP) Repair through a Vaginal Approach.

ETH.MESH.01279975-976 - Harel Gadot Email re Next step in SUI sling (Adkins Trial Exhibit P0686)

ETH.MESH.01310817-829

ETH.MESH.01317508-613 - TVT Factbook DHF - Revised 05.14.2001

ETH.MESH.01320328-33

ETH.MESH.01320351-67

ETH.MESH.01411037-039 - Prosima Study Results

ETH.MESH.01411037-039 - Summary re: Project Mint

ETH.MESH.0141137-039 Document re: summary of changes in mesh implant from Project Mint to final production.

ETH.MESH.01428106-112 - Carvigni, M. The use of synthetics in the treatment of pelvic organ prolapse. Curr Opin Urol 2001; 11: 429-435.

ETH.MESH.01593930-942 Prosima Clinical Expert Report (not signed or dated).

ETH.MESH.01595614-753

ETH.MESH.01612323-333

ETH.MESH.01613143-46

ETH.MESH.01638150 - Powerpoint: Gynecare Prosima ™ Pelvic Floor Repair System Backrgound; Halina Zyczynski, M.D.

ETH.MESH.01678340 - Email from Andrew Meek to Melissa Doyle et al. re: Approved Prosima Receptors.

ETH.MESH.01687850 (Adkins Trial Exhibit P4127)

ETH.MESH.01707963 - Ethicon Women's Health & Urology "Welcome Letter" to the EWH&U Pelvic Floor Repair Advisory Board Meeting.

ETH.MESH.01708116 to ETH.MESH.01708117 Email string, top one from Bart Pattyson to Georgia Long re: TVT Abbrevo and Prosima training; cc: Elizabeth Kolb, Andrew Meek.

ETH.MESH.01708180 - Chart listing financial information re: preceptors.

ETH.MESH.01708190 - Chart listing financial information re: preceptors.

ETH.MESH.01730626-629 Email string, top one from Dr. Antar to Bart Pattyson re: Prosima presentation.

ETH.MESH.01733531-535 - Kasturi, S. Pelvic magnetic resonance imaging for assessment of the efficacy of the Prolift system for pelvic organ prolapse. Am J Obstet Gynecol 2010; 203: 1.e1-1.e5

ETH.MESH.01739544 - TVT Secur CER 2010

ETH.MESH.01743909

ETH.MESH.01752532-535 - Jurgen Trzewik memo re mesh design argumentation issues (Engleman/Adkins Trial Exhibit P0705)

ETH.MESH.01758770-801 - TVT Secur Quality Board powerpoint (Engleman/Adkins Trial Exhibit P0706)

ETH.MESH.01775482 - Prosima letter delying launch

ETH.MESH.01782114-115 - (05.03.2006) Email string, top one from David Robinson to Carolyn Brennan re: Suzette email discussing problems with Prolift.

ETH.MESH.01782783-785 - (02.02.2006) Notes from meeting with Dr. V. Lucente and Dr. M. Murphy (Allentown, PA) to discuss Prolift RCT.

ETH.MESH.01782850-852 (Adkins Trial Exhibit P0716)

ETH.MESH.01784823-828 - Clinical Expert report-Laser Cut Mesh

ETH.MESH.01785259-260 - Email string re: +M relaxation

ETH.MESH.01803816 to ETH.MESH.01803818 Summary re: Project Mint

ETH.MESH.01805965

ETH.MESH.01808311-318 - Trip Report Michael Tracey

ETH.MESH.01809080-081 - Becky Leibowitz email to Paul Parisi and Dan Smith dated 12.14.2004 re comparison of laser-cut and machine-cut TVT mesh to meshes from competitive devices (Engleman/Adkins Trial Exhibit P0732)

ETH.MESH.01809082-83 - Memo re: VOC on new laser cut TVT mesh

ETH.MESH.01813259; ETH.MESH.02180759-61 - Email string with attachment re-Jeans Ideas.

ETH.MESH.01813975-78 - Email string re-FDA Prep-Plaintiff's Exhibit 460

ETH.MESH.01821586-587 Email from Allison London Brown to Ophelie Berthier, et al. re: Prosima November update; cc: Bob Roda, et al.

ETH.MESH.01822361-363 - Dan Smith Email regarding TVT Secur leading to less retention October 18, 2006

ETH.MESH.02001398-404 - Gynecare Prolift IFU (English Only)

ETH.MESH.02001398-473

ETH.MESH.02010349-362 - Prosima Clinical Expert Report signed by David Robinson

ETH.MESH.02017152-158 - (02.23.2007) Ethicon Expert Meeting: Meshes for Pelvic Floor Repair.

ETH.MESH.02020023-024 - Prosima ISO cytotoxicity biocompatibility

ETH.MESH.02026591-95 - MSDS-c4001 Polypropylene Homopolymer

ETH.MESH.02050884-909 - Prosima Key Procedural Steps

ETH.MESH.02059150-151 - May 24, 2006 Memo RE: First Post - Launch Complaint Review for the PROLIFT\* Pelvic Floor Repair System

ETH.MESH.02066770-771

ETH.MESH.02090196-209 - Plaintiff's Exhibit 4085-04.15.2008

ETH.MESH.02092919-921 - Prosima Clinical Strategy

ETH.MESH.02105223 (Adkins Trial Exhibit P0784)

ETH.MESH.02105765-771

ETH.MESH.02114615-616 Email string, top one from Libby Lewis to Donna Abely, et al. re: Remaining 2010 labs.

ETH.MESH.02124768-9

ETH.MESH.02136060-073 - Gynecare TVT Secur system design validation report (product) (Engleman Trial Exhibit P0789)

ETH.MESH.02148446-459 - Klosterhalfen, Junge, Klinge. The lightweight and large porous mesh concept for hernia repair (Engleman Trial Exhibit P0791)

ETH.MESH.02156379-380

ETH.MESH.02211890 - Test Report

ETH.MESH.02211912 - Annex 11: Porosity test on finished product - pelvic floor mesh.

ETH.MESH.02215374-375 - Jacquetin B. Prolene Soft (Gynecare) Mesh for Pelvic Organ Prolapse Surgical

Treatment: A Prospective Study of 264 Patients. Abstract 767

ETH.MESH.02215565-567 - Email from Scott Ciarrocca to multiple recipients re: a message from Barbara

Schwartz re: Prolift (01.02.2005).

ETH.MESH.02217343-44

ETH.MESH.02219584 - Scion PA-SUI Treatment Unmet Needs Exploratory Research

ETH.MESH.02229051 - cover sheet Biomechanics

ETH.MESH.02229051 - Video: "Biomechanics"

ETH.MESH.02229054 - cover sheet What to expect

ETH.MESH.02229054 - Video: "What to Expect"

ETH.MESH.02229055 - cover sheet VSD case series

ETH.MESH.02229055 - Video: "VSD Case Series 1"

ETH.MESH.02229057

ETH.MESH.02229059 - Abbrevo placement

ETH.MESH.02229063 - Secur placement.wmv

ETH.MESH.02229064 - TVT-O placement

ETH.MESH.02232685 - Marketing: "Your Proof: Her dance class."

ETH.MESH.02232773-801

ETH.MESH.02232854-874 - Prolift+M - Advanced User Discussion

ETH.MESH.02233126-187 - Prolift+M Educational Module

ETH.MESH.02233290

ETH.MESH.02233410 2009 US Sales Meeting Brief

ETH.MESH.02233410-416 - Prosima US Launch Pre-Market Preparation (Sept. 2009)

ETH.MESH.02233417 Prosima New Product Request Form

ETH.MESH.02233418 to ETH.MESH.02233438 Prosima - Surgical Technique

ETH.MESH.02233439 to ETH.MESH.02233451 A New Operation for Vaginal Prolapse Reapir Using Mesh and a Vaginal Support Device: 1 Year Anatomic and Functional Results of an International, Multicenter Study.

ETH.MESH.02233452 to ETH.MESH.02233467 Prosima - Background and Development History

ETH.MESH.02233468-538 - Prosima Prof Ed (71 slides)

ETH.MESH.02233539 to ETH.MESH.02233539 Prosima - New Product Request Form

ETH.MESH.02233540-625 - Prosima - 2009 Sales Training Program

ETH.MESH.02233605 to ETH.MESH.02233605 (B&W) Webinar Invite "The treatment of Symptomstiv Moderate Pelvic Organ Prolapse."

ETH.MESH.02233640 to ETH.MESH.02233640 (B&W) Prosima - Module 4: 2-Year Clinical Data

ETH.MESH.02233651 to ETH.MESH.02233673 One year Clinical Outcomes Following Prolapse Surgery with Non-Anchored Mesh and a Vaginal Support Device.

Results from the International Multicenter Gynecare Prosima ™ Study.

ETH.MESH.02233674 to ETH.MESH.02233692 (Marketing) "What is Gynecare Prosima Pelvic Floor Repair System?"

ETH.MESH.02233699-710 - Prosima - An Interview with Dr. Marcus P. Carey.

ETH.MESH.02233713 to ETH.MESH.02233714 Objective Success Rate Learning Guide

ETH.MESH.02233726 to ETH.MESH.02233727 Prosima Product Page on Ethicon-360

ETH.MESH.02233728 - Gynecare Prosima ™ Key Procedural Steps

ETH.MESH.02233751-833 - Prosima Prof Ed 2 (83 slides)

ETH.MESH.02233834 - (B&W) 2009 Sales Aid Guide

ETH.MESH.02233840 to ETH.MESH.02233841 MRI Flashcard "Prosima - The first fixationless mesh system that maintains anatomical position."

ETH.MESH.02233842 - Virtual Round Table Registration Form

ETH.MESH.02233843-849 - Clinical Study Findings Discussion for Gynecare Prosima ™ by Piet Hinoul (Audio Transcript).

ETH.MESH.02233851 - Document entitled "PROS-438-10-9/12 Prosima Short Procedural Video."

ETH.MESH.02233857-859 - AJOG Press Release (Draft)

ETH.MESH.02233857-859 - Prosima 1 year study letter

ETH.MESH.02233862 to ETH.MESH.02233880 AALG in booth presentation. "Proof in the Treatment of Pelvic Organ Prolapse" Douglas Van Drie, M.D.

ETH.MESH.02233881 to ETH.MESH.02233888 Zyczynski, H.M. "One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device." Am J Obstet Gynecol (2010) 203.

ETH.MESH.02233956 - Prosima Updates to Ethicon360

ETH.MESH.02233961 - Virtual Round Table Follow-up Letter.

ETH.MESH.02233962 - Virtual Round Table Follow-up Letter.

ETH.MESH.02233963 - Virtual Round Table Invitation

ETH.MESH.02233964 - (B&W) Prosima DVD

ETH.MESH.02234001 to ETH.MESH.02234002 (Marketing) The Gynecare Prosima ™ Pelvic Floor Repair System Story

ETH.MESH.02234005 to ETH.MESH.02234171 Prosima Sales Training Program

ETH.MESH.02234173 to ETH.MESH.02234177 Prosima Messgaging practice Coaching Check List

ETH.MESH.02234195-196 - Prosima Workshop Takeaway

ETH.MESH.02235456-73

ETH.MESH.02235474-502

ETH.MESH.02237107-115 - Introducing Gynecare Prosima for Ethicon Epiphany 247.

ETH.MESH.02237107-115 - Prosima Kevin Frost Presentation (moderate to severe)

ETH.MESH.02248778 - Mechanical vs Machine Cut (Laser.Ultrasonic) Mesh Particle loss less than 2 percent for both (January 19, 2005)

ETH.MESH.02248848 - Gynecare TVT Secur Powerpoint (Engleman/Adkins Trial Exhibit P0842)

ETH.MESH.02259836.Graft or no graft finl 11-21-04

ETH.MESH.02270724 - (07.19.2003) Email string, top one from Michel Cosson to Scott Ciarrocca re: Gynemesh holding force in tissue.

ETH.MESH.02270766-767 - (11.21.2003) Email string, top one from Michel Cosson to Scott Ciarrocca re: D'Art, risk question.

ETH.MESH.02270857-858 - (07.16.2004) Email from Laura Angelini to multiple recipients re: D'Art - Conversation with Prof. Jacquetin.

ETH.MESH.02286052-053 - Email string, top one from S. O'Bryan to S. Ciarrocca re: Prolift IFU

ETH.MESH.02293981 Email from Adrian Roji dated 7/19/11 re Approved FDA Notification Respo

ETH.MESH.02318553-554 - Gynecare Prosima ™ Combined Pelvic Floor Repair System Clinical Strategy.

ETH.MESH.02319312 - Memo re-TVT-base & TVT-O Complaint Review for Laser Cut Mesh Risk Analysis

ETH.MESH.02319408-09 - Email from David Robinson to Cyrus Guidry dated 4.17.07 enclosing powerpoint "Factors Related to Mesh Shrinkage - What do we know? A review of literature and internal studies" (Engleman/Adkins Trial Exhibit P0863)

ETH.MESH.02322037-039

**Production Materials** ETH.MESH.02322037-039 Email string, top one from Piet Hinoul to Aaron Kirkemo, et al. re: Neo clinical trial. ETH.MESH.02330766 ETH.MESH.02330767 - Marketing Materials for Prosima ETH.MESH.02330776 (TVTO-384-10-8.12) - TVT-O ETH.MESH.02340331-335 - TVT IFU (12.22.03 to 02.11.05) ETH.MESH.02340471-503 ETH.MESH.02340568-590 - TVT-Secur Instructions for Use (12/16/2005 to Discontinuance) (Engleman/Adkins Trial Exhibit P0871) ETH.MESH.02340829-835 - TVT-O IFU - (01.07.04 to 03.04.05) ETH.MESH.02341203-213 - TVT Abbrevo IFU ETH.MESH.02341203-266 - TVT Abbrevo IFU ETH.MESH.02341398-410 - Prosima IFU (6.18.10 to discontinuance) - English only 13 pages ETH.MESH.02341398-453 - Prosima IFU 2008 P21070 D ETH.MESH.02341454-459 - Gynecare Prolift IFU (English Only) ETH.MESH.02341454-521 ETH.MESH.02341522-527 - 2005 Gynecare Prolift IFU (English Only) ETH.MESH.02341658-664 - Gynecare Prolift IFU (English Only) ETH.MESH.02341658-733 ETH.MESH.02341734-740 - Prolift 2009-2010 IFU ETH.MESH.02341734-809 ETH.MESH.02342097 - Prolene Soft IFU (4.13.09 - 8.22.10) ETH.MESH.02342097 Prolene Soft IFU ETH.MESH.02342101 Prolene Soft IFU ETH.MESH.02342102 Prolene Mesh IFU ETH.MESH.02342152-54 Prolene Mesh IFU ETH.MESH.02342194-196 - Gynecare Gynemesh PS IFU (English Only) 03.20.03 - 03.30.06 ETH.MESH.02342218-220 - Gynecare Gynemesh PS IFU (English Only) ETH.MESH.02342250-252 - Gynecare Gynemesh PS IFU (English Only) ETH.MESH.02342278-279 - Gynecare Gynemesh PS IFU (English Only) ETH.MESH.02596085 - Letters to the Editor 2010; 1457 ETH.MESH.02597949-950 - Hinoul P, et al. "A "mesh" made in heaven: synergy between the urogynaecological device industry and evidence based medicine." ETH.MESH.02599918-920 - Email string, top one from Piet Hinoul to Kevin Frost re: 1-year Prosima Data Conference Call. ETH.MESH.02603812-821 - Dissection Techniques in Transvaginal Pelvic Organ Prolapse Repair with Synthetic Mesh ETH.MESH.02614610-624 ETH.MESH.02615519-658 ETH.MESH.02616825-827 Prolene Soft IFU ETH.MESH.02656825-834 - Issue Report TVT-O 2010 ETH.MESH.02658316 - Cover Letter ETH.MESH.02910418-421 - Axel Arnaud Email to Martin Weisberg et al dated 11.26.2002 re mini TVT mesh

adjustment (Engleman/Adkins Trial Exhibit P0933)
ETH.MESH.02916532-615 - Clinical Study Report - Evaluation of the TVT Secur System for Stress Urinary

ETH.MESH.02916532-615 - Clinical Study Report - Evaluation of the TVT Secur System for Stress Urinary Incontinence (Engleman/Adkins Trial Exhibit P0934)

## Case 3:20-cv-00851-MO Document 249-6 Filed 06/02/22 Page 225 of 259 Douglas Grier Materials List

#### **Production Materials**

ETH.MESH.02967410-412 - Study: Prosima (300-06-005); Plots/charts for 12-month vs. baseline safety analysis set.

ETH.MESH.03048942 - Document entitled "New" Mint January 05, 2006.

ETH.MESH.03049774-775 - Gynecare Prosima\* Combined Pelvic Floor Repair System: Clinical Strategy.

ETH.MESH.03056578-580 - Email string from Colin Urquhart to David Robinson and Judith Gauld re: Prosima\* investigator bulletin.

ETH.MESH.03086214-219 (Adkins Trial Exhibit P0946)

ETH.MESH.03109341 - Email string, top one from Judi Gauld to Halina Zyczynski re: Prosima well received at AUA.

ETH.MESH.03160821 - Email from Judith Gauld to Allison London Brown re: US Prosima Sites; cc: David Robinson, et al.

ETH.MESH.03160822 to ETH.MESH.03160823 Email string, top one from Judith Gauld to Stephanie Kute re: MINT Design Validation Dates; cc: Dan Smith, et al.

ETH.MESH.03160827 to ETH.MESH.03160828 Email string, top one from Colin Urquhart to Stephanie Kute re: Doctors contacted for DVal as of today; cc: Judith Gauld, et al.

ETH.MESH.03162936 to ETH.MESH.03162938 Email string from Judith Gauld to David Robinson and Jonathan Meek re: Marcus Carey US visit.

ETH.MESH.03172197-198 - Internal email from Harel Gadot to David Robinson dated 06.20.2006 re proposed RCT (Engleman/Adkins Trial Exhibit P0953)

ETH.MESH.03259439-40 - 4.24.2009 Gauld email chain re Green Journal

ETH.MESH.03361293 - Mesh Platform Review: Somerville, November, 2010.

ETH.MESH.03378923-933 - Prosima Patient Brochure - Stop Coping Start Living

ETH.MESH.03393725 to ETH.MESH.03339731 Sikirica, V, et al. "Sexual Function 12 Months Following Vaginal Prolapse Repair Augmented by Mesh and a Vaginal Support Device" ICS/IUGA (2010) Abstract

ETH.MESH.03396246 to ETH.MESH.03396246 VSD Patient Information (Slim Jim) - "Stop Coping Start Living."

ETH.MESH.03427757 to ETH.MESH.03427759 EWHU eClinical Compendium - Article Summary. Barber, M.D., et al. "Transobturator Tape Compared with Tension-free Vaginal Tape for the Treatment of Stress Urinary Incontinence: A Randomized Controlled Trial.

ETH.MESH.03427878-883 - TVT IFU - (11.29.10 to11.26.14)

ETH.MESH.03427878-945

ETH.MESH.03439842-846 Prosima Sales Aid Training Deck - "What could a truly tension-free repair mean for you and your patients?"

ETH.MESH.03440816-836 Prosima Revised Webinar Deck - Overview

ETH.MESH.03458123-138

ETH.MESH.03459088-104

ETH.MESH.03460813-853 - Prolift Surgeon's Resource Monograph, approved 4.13.2007

ETH.MESH.03460813-884 - Prolift Surgeons Resource Monograph

ETH.MESH.03466382-383 - DX24665 - Bedestani email re Prosima

ETH.MESH.03471308 Chart entitled "Pedm Monthly Status."

ETH.MESH.03497846-847 - MDD Complaint Form Complaint ID CC1007005

ETH.MESH.03612364 - Gynecare Prosima Pelvic Floor Repair Preceptorship, Course Overview.

ETH.MESH.03620412-413

ETH.MESH.03620414

ETH.MESH.03620415

ETH.MESH.03626267-269 - Email string, top one from Jennifer Paradise to Susie Chilcoat re: Prosima Professional Education Slide Deck Conference Call.

ETH.MESH.03643186 - Ethicon Women's Health and Urology Brand Equity Study Final Report Powerpoint (Engleman/Adkins Trial Exhibit P1008)

ETH.MESH.03643392-395 - Email string, top one from Jennifer Paradise to Adrian Roji, et al. re: Approved for distribution: FDA Notification FAQS and Customer Letter.

ETH.MESH.03667696-704 - Company Procedure for US Regulatory Affairs Review of Promotion and Advertising Materials for Medical Devices.

ETH.MESH.0370392 (3914 2007-08-22) - 2007 TVT-Secur

ETH.MESH.03715787-793 - Gynemesh PS CER (2002) - Weisberg

ETH.MESH.03715978 - Weisberg email re: TVT question.

ETH.MESH.03725540-553 - Memo dated 07.06.2010 re EWHU innovation counsel (Engleman Trial Exhibit P2572)

ETH.MESH.03736120-127 - Gynemesh PS: A New Mesh for Pelvic Floor Repair Early Clinical Experience

ETH.MESH.03751819

ETH.MESH.03845446-450 - Darryl Harkness email to Aran Maree dated 10.30.2007 re secur update presented in at WW marketing meeting (Engleman Trial Exhibit P1063)

ETH.MESH.03895925-927 - DX24789 - Bedestani email re Prosima

ETH.MESH.03905472-77 - Email string re-TVT recommendation from Dr. Alex Wang

ETH.MESH.03905968-975 - 2005 Prolift Patient Brochure: POP, Get the facts, be informed, make your best decision

ETH.MESH.03905976-991 - Prolift Patient Brochure: POP, Get the facts, be informed, make your best decision

ETH.MESH.03905992-6000

ETH.MESH.03906001-6020 - Prosima and Prolift+M Patient Brochure: What You Should Know About Pelvic Organ Prolapse. Stop Coping. Start Living. Dated 11/9/2009

ETH.MESH.03906001-6020 - Prosima Brochure (11.09.2009)

ETH.MESH.03906037-052 - Prolift Patient Brochure: Treatment Options for POP, stop coping, start living

ETH.MESH.03907468-9 - Second Generation TVT - by Axel Arnaud

ETH.MESH.03910175-177 - Email string re - Soft Prolene (Adkins Trial Exhibit P1080)

ETH.MESH.03910418-21 - Email string re-Mini TVT - mesh adjustment

ETH.MESH.03911107-08 - Email string re-TVT complications (an Prof. Hausler)

ETH.MESH.03911901-910 - Deprest J, et al. The biology behind fascial defects and the use of implants in pelvic organ prolapse repair. Int Urogynecol J (2006)

ETH.MESH.03913357-359 - Axel Arnaud Email 5.31.07 Re TVT TVT-O

ETH.MESH.03916905-913 - Plaintiff's Exhibit 3827

ETH.MESH.03917375-378 - (11.26.2002) Email string, top one from Martin Weisberg to Dr. Richard Juraschek, et al. re: Mini TVT - mesh adjustment.

ETH.MESH.03921355-156 - Miller, D. Prospective Clinical Assessment of the Total Vaginal Mesh (TVM) Technique for Treatment of Pelvic Organ Prolapse - 6 and 12 month results.

ETH.MESH.03921612 - E-mail from Ralf Gotter to Arnaud and Gadot dated 11.30.2006 regarding, "The more procedures the more problems." (Engleman/Adkins Trial Exhibit P1096)

ETH.MESH.03922953 (Adkins Trial Exhibit P1100)

ETH.MESH.03923121-122 - Andrew Beveridge email to Julie Hocknell and Axel Arnaud dated 02.20.2008 re trip to Israel (TVT-S complication summary) (Engleman/Adkins Trial Exhibit P1102)

ETH.MESH.03924557-586 - Meshes in Pelvic Floor Repair-Findings from literature review and conversations-interviews with surgeons, June 6, 2000.

ETH.MESH.03930120-123 - Nilsson C. Seven-Year Follow-up of the Tension-Free Vaginal Tape Procedure for Treatment of Urinary Incontinence. Obstet Gynecol 2004; 104(6): 1259-62

ETH.MESH.03932909-911 - Confidential - History of TVT-O

ETH.MESH.03932912-914 - The History of TVT

ETH.MESH.03941623 - DeLeval Email RE: TVT ABBREVO ALERT - French and English Email and English Translation Certification Plaintiff's Exhibit 3619- Perry

ETH.MESH.03958008

ETH.MESH.03959337 - Prolift+M vs. Prosima - 2 year results

ETH.MESH.03962244 Dear Surgeon letter 7/18/11

ETH.MESH.03984409-410 Email string, top one from Scott Finley to Greg Prine re: Pelvic Floor Repair Customer Meeting.

ETH.MESH.03989722-723 Email string, top one from Jim Gatewood to Rebecca Ryder re: Prosima 2 Year data Dinner.

ETH.MESH.03989781-782 Email from Jim Gatewood to Marilyn Valdes re: Norfolk, VA, Dec 2, 2010 Prosima Awareness Dinner Information.

ETH.MESH.03991591-592 Memo re: Gynecare Studies; created by Randall Gore.

ETH.MESH.04005090-091 - Ethicon informs FDA of discontinuation

ETH.MESH.04005092-093 - Ethicon's Notification to FDA to Decommercialize

ETH.MESH.04005095-096 - Ethicon's Notification to FDA regarding Decommercialization

ETH.MESH.04042511-512 Slack, M., et al. Presentation Title: "Clinical Experience of a Novel Vaginal Support Device and Balloon used to Simplify Mesh Augmented Vaginal surgery for Prolapse."

ETH.MESH.04046302 - Powerpoint: TVT and TVT-O Update

ETH.MESH.04048515-520 - KOL Interview with Carl Nilsson re intent for next generation mini sling, intent for 2 distinct devices O and R and breakdown of current TVT-S usage in US (Engleman/Adkins Trial Exhibit P1128)

ETH.MESH.04077172 - Powerpoint: Gynecare LatAm Moments at IUGA Congress 2010

ETH.MESH.04079609

ETH.MESH.04081189 - Meeting Agenda

ETH.MESH.04082973 - Possible Complications for Surgeries to Correct POP and SUI

ETH.MESH.04092868 - Email re: 10100080654 and TVT IFUs

ETH.MESH.04093125 - Meng Chen email to Bryan Lisa dated 11.30.2006 re TVT IFUs on tape extrusion, exposure and erosion (Engleman/Adkins Trial Exhibit P1139)

ETH.MESH.04181761-762 - Gynecare Prolift Pelvic Floor Repair

ETH.MESH.04201880 - Prosima Training Deck 2

ETH.MESH.04202101 (2008-448)

ETH.MESH.04206959

ETH.MESH.04381806-819 Literature Review on Biocompatibility of Prolene Sutures and Impants

ETH.MESH.04385229-245 (Adkins Trial Exhibit P1177)

ETH.MESH.04427456-457 FDA Letter re: K063562 Gynecare Prosima Pelvic Floor Repair Systems

ETH.MESH.04465690 - MSE0079 - Material Specification for Gynemesh PS - Revision A

ETH.MESH.04474731 - Ethicon's Cover Letter Response to TVT Secur 522 Order

ETH.MESH.04474756-760 - Hota, et al. (2012) TVT Secur (Hammock) versus TVT Obturator: a randomized trial of suburethral sling operative procedures. Female Pelvic Med Reconstr Surg; 18(1), January/February 2012 (Engleman/Adkins Trial Exhibit P1185)

ETH.MESH.04476265-272 - April 24 2012 email to FDA

ETH.MESH.04499687-742 - (Adkins Trial Exhibit P0036)

ETH.MESH.04543335 - Pelvic Organ Prolapse Surgical Mesh Discussion call in information 9/12/11

ETH.MESH.04543336 - Pelvic Organ Prolapse Surgical Mesh Discussion call in information 9/12/11

ETH.MESH.04548931-35

ETH.MESH.04550996-997 Email string, top one from Piet Hinoul to Marcus Carey and Richard Gooding re: Prosima VSD.

ETH.MESH.04551757-795 - Email with attachment from Piet Hinoul to Jeffrey Hammond, Dr. James Hart, et al. regarding Benefit risk profile TVM

ETH.MESH.04551946 Ethicon Gynecare WW Commercialization Decision - US Surgeon Letter 6/1/12

ETH.MESH.04554662 Ethicon Gynecare WW Commercialization Decision - US Frequently Asked Questions 6/1/12

ETH.MESH.04554687 - FDA letter to Ethicon re 522 Orders (Kanerviko 2013-08-22 29)

ETH.MESH.04558399-409 - Iglesia C. Vaginal Mesh for Prolapse: A Randomized Controlled Trial. Obstet Gynecol 2010;116:293-303

ETH.MESH.04567040-44 - FDA's Response to proposed study plan-04.02.2012

ETH.MESH.04567080 - FDA's Resposne to Discontinuation and Agreement to Hold 522 Responses

ETH.MESH.04567174 US Discussion Guide for Use with Customers 5/15/12

ETH.MESH.04567674 Core Messages 5/15/12

ETH.MESH.04567677 Frequently asked questions 5/15/12

ETH.MESH.04567680 - Message from Laura Angelini to Internal WW Associates 5/15/12

ETH.MESH.04567686 - US Sales Call Script for Matt Henderson 5/15/12

ETH.MESH.04567695 - Ethicon Gynecare WW Commercialization Decision - Core Messages 6/1/12

ETH.MESH.04567698 - Ethicon Gynecare WW Commercialization Decision - Standby Statement 6/1/12

ETH.MESH.04567707 - Ethicon Gynecare WW Commercialization Decision - Chuck Austin Message to WW General Surgery Employees 6/1/12

ETH.MESH.04567726 - Ethicon Gynecare WW Commercialization Decision - Tim Schmid message to US General Surgery Employees 6/1/12

ETH.MESH.04568519 - Email from Matt Henderson to Tim Schmid re: 522 Communication Recap.

ETH.MESH.04568717-719 - DX24785 - Khandwala email re Prolift+M

ETH.MESH.04925426 - DX10341 Beath email to Kanerviko

ETH.MESH.04926150-151 - DX24802 - Piet discussing 522 order

ETH.MESH.04926191-92

ETH.MESH.04927339-340 - FDA's Resposne to Discontinuation Notification-07.09.2012

ETH.MESH.04927339-340 - Prosima 2012 FDA

ETH.MESH.04931596 - Kanerviko email re 40000 page response to 522

ETH.MESH.04938298-299 - Piet Hinoul Email Re: Prof. de Leval - TVT Abbrevo

ETH.MESH.04939001

ETH.MESH.04941016 - Lightweight Mesh Developments (Powerpoint)

ETH.MESH.04945231-239 - Email string re-Ultrapro vs Prolene Soft Mesh

ETH.MESH.04945496 - Bernd Klosterhalfen Email Re: Ultrapro vs. Prolene Soft Mesh April 18, 2005

ETH.MESH.04984220-221 - DX24790 - Lucente email

ETH.MESH.05009194

ETH.MESH.05092843-843 Chart listing lab schedule for August 11th.

ETH.MESH.05106233-234 Email string, top one from Kevin Frost to danhalt@gmail.com, et al. re: Reminder:

Prosima Professional Education Slide Deck Conference Call Tonight 7pm EST.

ETH.MESH.05164225 to ETH.MESH.05164226 EWHU eClinical Compendium - Article Summary. Reisenauer, C., et al. "Anatomic study of prolapse surgery with nonanchored mesg and a vaginal support device."

ETH.MESH.05165675 to ETH.MESH.05165677 EWHU eClinical Compendium - Article Summary. Barber, M.D., et al. "Defining success after surgery for pelvic organ prolapse." Obstet Gynecol (2009) 114:600-609.

ETH.MESH.05217098-100 FDA Clearance Letter, Modified PROLENE

ETH.MESH.05217103-144 Letter to FDA re: Notification of Intent

ETH.MESH.05222673-705

ETH.MESH.05222686-88 - TVT IFU (4th version) 4.7.06-10.7.08

ETH.MESH.052235354-85

ETH.MESH.05225380-384 - TVT IFU - (09.08.00 to 11.26.03)

ETH.MESH.05234758-762 - Dr. Kerstein Spychaj memo dated 12.12.2006 re State of the knowledge in "mesh shrinkage" - what do we know? (Engleman/Adkins Trial Exhibit P1235)

ETH.MESH.05320909 - 2008 Treatment of Stress Urinary Incontinence with Gynecare TVT Secur System

ETH.MESH.05321899

ETH.MESH.05321900

ETH.MESH.05337217-220 - Email string, top one from D. Miller to J. Paradise, et al

ETH.MESH.05343480 to ETH.MESH.05343482 Email string, top one from Joseph Lanza to Bart Pattyson re: Review EWHU IUGA events.

ETH.MESH.05343757 to ETH.MESH.05343758 Email string, top one from Kevin Frost to Bart Pattyson re: July 31 Heads Up; cc: Lissette Caro-Rosado.

ETH.MESH.05347751-762 - Email string re Investigator-initiated studied policy

ETH.MESH.05439518-22 - Sunoco MSDS

ETH.MESH.05446127-139 - Joerg Holste email to Dr. Dieter Engel et al dated 03.13.2006re mesh and tissue contraction in animal (Engleman/Adkins Trial Exhibit P1846)

ETH.MESH.05469908-912 Email string, top one from Thomas Barbolt to Dr. Joerg Holste, et al. re: Ultrapro; cc: Laura Angelini, et al.

ETH.MESH.05475773-822 - Borist Batke powerpoint - The (clinical) argument of lightweight mesh in abdominal surgery (Engleman/Adkins Trial Exhibit P1274)

ETH.MESH.05479411 - The (clinical) argument of lightweight mesh in abdominal surgery

ETH.MESH.05479535 - Mesh porosity chart (Engleman Trial Exhibit P1278)

ETH.MESH.05559108-109 (Adkins Trial Exhibit P1318)

ETH.MESH.05571741 to ETH.MESH.05571741 Email string, top one from Jim Gatewood to Robert Zipfel re: Gynecare Prof Ed - Approved: Request for Speaker Event.

ETH.MESH.05573916 to ETH.MESH.05573917 Email string, top one from Kevin Frost to Jennifer Paradise re: Prosima VRT Reminder - Honoraria Payments; cc: Paul Parisi.

ETH.MESH.05588123-126 - Stephen Wohlert Email - AW: How inert is polypropylene? July 9, 2007

ETH.MESH.05600916-923 - Background Information Gynecare Pelvic Floor Repair Products and Gynecare TVT Secur (Engleman Trial Exhibit P1327)

ETH.MESH.05644163-171 - Pelvic Floor Repair-Surgeon's Feed-back on Mesh Concept

ETH.MESH.05741094 - Email from Rhonda Peebles to Samuel Sheelu, et al. re: Additional room for Ask the Expert sessions; cc: Alyson Wess, et al.

ETH.MESH.05741890 to ETH.MESH.05741891 Email string, top one from Christopher Teasdale to Tom Affeld, et al. re: Additional room for Ask the Experts sessions.

ETH.MESH.05779953-7

ETH.MESH.05795097-104 (Adkins Trial Exhibit P1352)

ETH.MESH.05795421-508

ETH.MESH.05795509-536

ETH.MESH.05795537-99

ETH.MESH.05795600-21

ETH.MESH.05799233-39 - TVT Exact IFU

ETH.MESH.05820723 - Dear Surgeon Letter re Discontinuation

ETH.MESH.05835298-308 - Pelvic Organ Prolapse - Patient Counseling Guide.

ETH.MESH.05837063 to ETH.MESH.05837110 Pelvic Organ Prolapse Value Dossier. Gynecare Prolift, Gynecare Prolift +M, Gynecare Prosima.

ETH.MESH.05837242 - DX23938 - Letter re FDA 2011 Notice

ETH.MESH.05840629 to ETH.MESH.05840629 Powerpoint Presentation entitled "Continuum of Education."

ETH.MESH.05918776 - Email re: Marlex Experience

ETH.MESH.05922038 to ETH.MESH.05922038 Letter from Patricia Nevar to Jaime Sepulveda, M.D. re: Secrecy Agreement for Prosima.

ETH.MESH.05947160 to ETH.MESH.05947163 Email from Patricia Holland to Andre Fontes re: Partnership Plus Follow up Gynecare Reminder; cc: Fernando Nassif, et al.

ETH.MESH.05958248 - Surgeons Resource Monograph

ETH.MESH.05958527-530

ETH.MESH.05960623

ETH.MESH.05967586-587 Email string, top one from Robert Zipfel to Susie Chilcoat re: Prosima Preceptor-Led Virtual Round Tables (VRTs) faculty payment.

ETH.MESH.05998835-836 - Piet Hinoul Email Re: ALERTE TVT ABBREVO

ETH.MESH.06087210-212

ETH.MESH.06087471-472

ETH.MESH.06087513-514

ETH.MESH.06090245

ETH.MESH.06113091 to ETH.MESH.06113092 Email from Debra Mayfield to DL-ETHUSSO EWHU WESTERN REGION re: Prosima VRT Invitation Plan - due Jan 28.

ETH.MESH.06124656 to ETH.MESH.06124657 Email string, top one from Andrew Meek to Bart Pattyson re: Prosima training.

ETH.MESH.06124954 to ETH.MESH.06124955 Email string, top one from Bart Pattyson to Marcos Fujihara re: Prosima training in Miami with Dr. Jaime Sepulveda.

ETH.MESH.06125000 to ETH.MESH.06125001 Email string, top one from Bart Pattyson to Robert Zipfel re: Prosima in LATAM.

ETH.MESH.06125058 to ETH.MESH.06125058 Email from Bart Pattyson to Eugene Brohee re: June 21 - Latin America doctors in town; cc: Selena Lessa.

ETH.MESH.06125098 to ETH.MESH.06125098 Email string, top one from Bart Pattyson to Georgia Long re: updated agenda - May 8th.

ETH.MESH.06125277 to ETH.MESH.06125277 Email string, top one from Marcos Fujihara to Bart Pattyson, et al. re: Prosima presentation in Miami.

ETH.MESH.06125309 to ETH.MESH.06125309 Email string, top one from Robert Zipfel to Bart Pattyson re: Prosima in LATAM.

ETH.MESH.06125502 to ETH.MESH.06125502 Email string, top one from Georgia Long to Bart Pattyson re: may 8th.

ETH.MESH.06151466 to ETH.MESH.06151467 Email string, top one from David Robinson to Judith Gauld re: Jaime Sepulveda.

ETH.MESH.06151983-84 - David Robinson email to Allison London Brown dated 08.26.2006 re TVT-S results to week 5 (31 patients) (Engleman/Adkins Trial Exhibit P1403)

ETH.MESH.06238611 to ETH.MESH.06238611 Email from Mark Kenyon to Aaron Kirkemo re: NEO Surgical Guide - Role & Responsibilities; cc: Vincenza Zaddem.

ETH.MESH.06255523 to ETH.MESH.06255534 Gynecare Prosima ™ Pelvic Floor Repair System. "An Expert Interview with Dr. Marcus P. Carey, MBBS, FRANZCOG, CU, the Inventor of the Gynecare Prosima System."

ETH.MESH.06255523-34 - Gynecare Prosima Pelvic Floor Repair System: An expert interview with Dr. Marcus P. Carey, MBBS, FRANZCOG, CU, the inventor of the Gynecare Prosima system

ETH.MESH.06382976-987 - Jia, X. Efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse: systematic review and meta-analysis. BJOG 2008; 115: 1350-1361

ETH.MESH.06388151 to ETH.MESH.06388151 Powerpoint: Prolift Pelvic Floor Repair - MDV Reported Complaints

ETH.MESH.06400722 - GYNECARE GYNEMESH PS CE Mark Technical File

ETH.MESH.06480608 to ETH.MESH.06480609 Email string, top one from Judith Gauld to Stephanie Kute re: MINT Design Validation Dates; cc: Dan Smith, et al.

ETH.MESH.06482821 to ETH.MESH.06482822 Email from Judith Gauld to Tony Smith re: Prosima Investigator Meeting; cc: David Robinson.

ETH.MESH.06585815 to ETH.MESH.06585815 Powerpoint: Agenda

ETH.MESH.06591558 to ETH.MESH.06591559 Email string, top one from Tom Affeld to Shwetal Narvekar re: Prelaunch Awareness for Prosima with Dr. Marcus Carey; cc: Bart Pattyson, et al.

ETH.MESH.06592243 - 09.14.2012 Email from Carl Nilsson to Laura Angelini

ETH.MESH.06695438 - Justification for Utilizing the Elasticity Test as the Elongation Requirements on TVT LCM

ETH.MESH.06769156 - Powerpoint: A New Operation for Vaginal Prolapse Repair Using Mesh and a Vaginal Support Device: 1 Year Anatomic and Functional Results of an International, Multicenter Study. Mark Slack, Cambridge, UK for the Prosima Study Group.

ETH.MESH.06861281 - Scott Ciarrocca email to David Robinson and Dan Smith dated 01.21.2008 re TVT Secur Data (Engleman Trial Exhibit P1437)

ETH.MESH.06887138-40 - Waltregny email written on behalf of Professor de Leval.

ETH.MESH.06887244 - 07.16.04 David Waltregny email to Dan Smith re: TVT-O.

ETH.MESH.06893564-565 - Email from Folke Flam to Aviram Suchard dated 09.25.2006 re feedback after using TVT Secur after the launch (Engleman/Adkins Trial Exhibit P1452)

ETH.MESH.06894461-467 - Klinge 2002 Impact of polymer pore size on the interface scar formation in a rat model (Engleman Trial Exhibit P1454)

ETH.MESH.06917699-704 - Form For Customer Requirements Specification (CRS) For Project TVT-O PA

ETH.MESH.06923868-71 - TVTO-PA Clinical Strategy - 8.21.13 Exhibit A.M. Mitchell T-2177

ETH.MESH.06927248-249 - Dan Smith email to Paul DeCosta et al dated 03.19.2010 re Scion Evaluation Comparison file (EnglemanAdkins Trial Exhibit P1460)

ETH.MESH.07090179-181 (Adkins Trial Exhibit P1463)

ETH.MESH.07105727 - Email string, top one from Laura Vellucci to Colin Urquhart re: Prosima publication.

ETH.MESH.07181042-043 (Adkins Trial Exhibit P1464)

ETH.MESH.07186593-624 (Adkins Trial Exhibit P1467)

ETH.MESH.07189091 - Powerpoint: From presentation to publication: ensuring quality in the reporting of urogynaecology research. IUGA "This house believes that industry sponsorship has a corrosive influence on standards of scientific reporting." Conflict of interests: Piet Hinoul, M.D.

ETH.MESH.07190144 to ETH.MESH.07090145 Email string, top one from Judi Gauld to Piet Hinoul, Colin Urquhart re: +M Abstract.

ETH.MESH.07192929 - Investigating Mesh Erosion in Pelvic Floor Repair Powerpoint

ETH.MESH.07201006 - Prolift Professional Education Slide Deck (2007)

ETH.MESH.07219196-209 Clinical Expert Report - Prosima ™ signed by David Robinson.

ETH.MESH.07226579-590 - 2000 - TVT CER

ETH.MESH.07229215-245 Clinical Expert Report - Prosima ™ signed by Piet Hinoul.

ETH.MESH.07246690-719

ETH.MESH.07296496 - Chart listing Week Schedule and Lab Flow.

ETH.MESH.07308636-637 Email from Tom Affeld to Clifford Volpe, et al. re: Surgeon's view on Prosima; cc: Lissette Caro-Rosado, et al.

ETH.MESH.07324554-555

ETH.MESH.07351297

ETH.MESH.07374762 to ETH.MESH.07374763 Email from Lissette Caro-Rosado to Jaime Sepulveda, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattyson, et al.

ETH.MESH.07379573 to ETH.MESH.07379574 Email string, top one from Kevin Frost to Ahmet Bedestani, et al. re: Purpose; cc: Matt Henderson, et al.

ETH.MESH.07383398 - FW Information Regarding FDA Notification of Use of Mesh in Pelvic Surgery

ETH.MESH.07383730-731 - Email string re-Ultrapro mesh information-identical mesh to Prolift +M

ETH.MESH.07384790-791 Email string, top one from Robert Zipfel to Lissette Caro-Rosado re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones, and Schlafstein on Monday Jan 4, 2010.

ETH.MESH.07452663 - Power Point - Neuchatel Particles in TVT-O Blisters

ETH.MESH.07462313 Email from Adrian Roji dated 8/19/11 re update message to the field re FDA notification response

ETH.MESH.07587090 to ETH.MESH.07587091 Email string, top one from Judith Gauld to Patricia Nevar re: Dr. Sepulveda; cc: Colin Urquhart.

ETH.MESH.07628243 to ETH.MESH.07628243 EWH&U Gynecare Prosima ™ Pelvic Floor Repair System Faculty Checklist.

ETH.MESH.07630654 to ETH.MESH.07630654 Email string, top one from Greg Prine to Stevan Barendse, Robert Zipfel re: Prosima targets.

ETH.MESH.07631488 to ETH.MESH.07631488 Email string, top one from Selena Lessa to Robert Zipfel re: Prosima course with Sepulveda.

ETH.MESH.07631752 to ETH.MESH.07631753 Email string, top one from Eric Globerman to Nicole Huffman re: Prosima course; cc: Robert Zipfel.

ETH.MESH.07631967 to ETH.MESH.07631968 Email string, top one from Stacy Hoffman to Robert Zipfel, Kimberly Heath re: Prosima Lab.

ETH.MESH.07632042 to ETH.MESH.07632042 Event request form for Sepulveda Preceptorship.

ETH.MESH.07632042 to ETH.MESH.07632043 Email from Kevin Frost to danhalt@gmail.com, et al. re: Save the Date: Prosima Faculty Conference Call 7/20 at 7pm EST; cc: Jennifer Paradise.

ETH.MESH.07636090 to ETH.MESH.07636090 Prosima Cadaver Lab Invitation

ETH.MESH.07653362 to ETH.MESH.07653363 Email string, top one from Tommaso Santini to Kevin Frost, et al. re: US Surgeon; cc: Tom Affeld.

## Case 3:20-cv-00851-MO Document 249-6 Filed 06/02/22 Page 233 of 259 Douglas Grier Materials List

#### **Production Materials**

ETH.MESH.07898852-871 - Linda Nichols email to Linda Answell et al dated 12.01.2004 re TVTx Charter document for 12/06 GAT meeting (Engleman/Adkins Trial Exhibit P1527)

ETH.MESH.07903682-683

ETH.MESH.07931680-681 Email string, top one from Bart Pattyson to Jeff Hsieh re: Prosima Professional Education Slide Deck Conference Call.

ETH.MESH.07951163 - Document re: Prosima's apical/anatomical success rates and functional outcomes.

ETH.MESH.07953429-433 - EWH&U 2011 Field Visit Letter

ETH.MESH.07977911

ETH.MESH.08003173-180

ETH.MESH.08003181-196

ETH.MESH.08003197-212

ETH.MESH.08003215-230 - Ethicon Copy Review Submission form: GYNECARE TVT Tension-free Support for Incontinence Patient Brochure. Submitted by Robin Osman dated 07.12.2006 (Engleman Trial Exhibit P1536)

ETH.MESH.08003231-246

ETH.MESH.08003247-262

ETH.MESH.08003263-278 - Ethicon Copy Review Submission form: GYNECARE TVT Tension-free Support for Incontinence Patient Brochure (Including TVT Secur) dated 05.29.2009 (Engleman Trial Exhibit P1539)

ETH.MESH.08003279-294

ETH.MESH.08003295-302

ETH.MESH.08003303-318

ETH.MESH.08021804 to ETH.MESH.08021807 Email string, top one from Libby Lewis to Kenneth Pagel, et al. re: Journal Club - trocar-less vaginal mesh kits.

ETH.MESH.08023741 to ETH.MESH.08023744 Email string, top one from Scott Miller to Jonathan Fernandez re: Prosima Take Away Messages.

ETH.MESH.08033153 - Document entitled "Prevalence and risk factors for mesh erosion after laparoscopic-assisted sacrocolpopexy." Author(s) Jasmine Tan-Kim, Shawn A, Menefree, Karl M, Luber, Charles W. Nager, Emily S. Lukacz.

ETH.MESH.08041930-931 - Michelle Irvin email RE 12.08.2010 post call notes (Engleman Trial Exhibit P2563)

ETH.MESH.08048738-740 Email from David Jackson to Selena Lessa re: Prosima course with Sepulveda.

ETH.MESH.08066452

ETH.MESH.08107354

ETH.MESH.08117473

ETH.MESH.08117625-626

ETH.MESH.08135444 - Gynecare Prosima - Pelvic Floor Repair System Proctorship

ETH.MESH.08139049-118 Pelvic Organ Prolapse - The Role of Prosima. Author: Mark Slack.

ETH.MESH.08156958

ETH.MESH.08161765 - Email from Suzy Taylor to Jared Aldridge, et al. re: Follow up to FDA Mesh Advisory.

ETH.MESH.08167452-453 (Adkins Trial Exhibit P1553)

ETH.MESH.08169582-620 Surgical Practice of POP survey on Survey Monkey.

ETH.MESH.08290691

ETH.MESH.08299913-917 - Nilsson C. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J 2013; 24(8): 1265-9 [9.11.13 Exhibit T-1271]

ETH.MESH.08307644-45 - 4.05.2013 - Email from P. Hinoul to G. Callen re: RCT data (with attachments).

ETH.MESH.08309057-092 Document entitled "Benefit-Risk Profile of Ethicon, Inc.'s Pelvic Organ Prolapse Mesh Repair Products."

ETH.MESH.08315779 - Clinical Expert report-09.25.2012

ETH.MESH.08328772-922 - Prosima - Patient Brochure Literature

ETH.MESH.08334244-45 - Email string re-Photographs of LCM vs MCM with powerpoint attachment

ETH.MESH.08375158 to ETH.MESH.08375159 Email string, top one from Larry Gillihan to Kenneth Pagel, Jason Hernandez re: New Product Tabs - TVT Abbrevo, Prosima, TVT Exact.

ETH.MESH.08384247

ETH.MESH.08384270 - Email string, top one from Lisa Pitts to Paul Saliba re: Prosima pearls from Dr. Garris.

ETH.MESH.08421628 Ethicon Gynecare WW Commercialization Decision - US Customer Discussion Guide 6/1/12

ETH.MESH.08476311 - Cytotoxicity assessment of Ulstem sling

ETH.MESH.08492824 - Strategic Business Team Meeting - Meeting Notes

ETH.MESH.08565137-141

ETH.MESH.08568006-012 - Abstracts Feola 2011 - Abs Stress-shielding: the impact of mesh stiffness on vaginal function (Engleman Trial Exhibit P2564)

ETH.MESH.08640676 Jones email 4/04/08 re Prosima update for RBDs

ETH.MESH.08791917

ETH.MESH.08945734 to ETH.MESH.08945735 ICS-IUGA 2010 Abstract Form. "Ultrasound assessment 6 months following vaginal prolapse surgery using polypropylene implants and a vaginal support device."

ETH.MESH.08945742 to ETH.MESH.08945744 Presentation Title: A New Operation for Vaginal Prolapse Repair using Mesh and a Vaginal Support Device: 1 Year Anatomic and Functional Results of an International, Multicentre Study." Presenter: Slack, M., et al.

ETH.MESH.08945836 to ETH.MESH.08945840 Document entitled "Gynecare Prosima Claims List."

ETH.MESH.08948364 to ETH.MESH.08948365 Email string, top one from Kevin Frost to William Rush re: Save the Date: Prosima 2 Year Clinical Data Review; cc: Tom Affeld.

ETH.MESH.08951725 to ETH.MESH.08951726 Email string, top one from Tom Affeld to Kevin Frosr re: Prosima 2 year summary for eClinical Compendium.

ETH.MESH.08961175-08961176

ETH.MESH.08962682 to ETH.MESH.08962683 Email from Helen Wong to Kevin Frost re: Sepulveda's comment on the VRT; cc: Jenny Krieger, et al.

ETH.MESH.08962684 to ETH.MESH.08962685 Email string, top one from Jenny Krieger to Kevin Frost re: Reminder: Prosima Teleconference today.

ETH.MESH.08971152 to ETH.MESH.08971153 Email string, top one from Kevin Frost to Libby Lewis re: Prosima VRT Invitation plan - due Jan 28.

ETH.MESH.08971269 to ETH.MESH.08971270 Email string, top one from Kevin Frost to Aaron Kirkemo, Piet Hinoul re: Prosima VRT: fill-in.

ETH.MESH.08971271 to ETH.MESH.08971272 Email string, top one from Kevin Frost to Marilyn Valdes re: Dr. Sepulveda availability on 1/31.

ETH.MESH.08971309 to ETH.MESH.08971314 Email string, top one from Kevin Frost to Helen Wong re: Dr. Sepulveda's 1/31 VRT; cc: Jenny Krieger.

ETH.MESH.08988155 to ETH.MESH.08988155 Powerpoint: Gynecare Prosima ™ Pelvic Floor Repair System: Background. Halina Zyczynski, M.D.

ETH.MESH.08988298 to ETH.MESH.08988417 EBM - Pelvic Organ Prolapse Clinical References: 2002-2011, including Prolift, Prolift+M, Prosima, Gynemesh. Searcher: Kerry Kushinka.

ETH.MESH.09050450 to ETH.MESH.09050450 Memoradum from David Robinson re: the compatibility if estrogen creams with Prosima balloon and vaginal support device. (Not signed).

ETH.MESH.09100506 - Prolift Professional Education Slide Deck (2005)

ETH.MESH.09128451 - Chart entitled "Faculty Training."

ETH.MESH.09128545 - Pelvic Organ Prolapse Surgical Mesh Discussion call in information 8/25/11

ETH.MESH.09138054 to ETH.MESH.09138055 Information re: Jaime Sepulveda, M.D. and Arthur Mourtzinos, M.D.

ETH.MESH.09142383 to ETH.MESH.09142384 Email from Kevin Frost to danhalt@gmail.com, et al. re: Save the Date: Prosima Faculty Conference Call 7/20 at 7pm EST; cc: Jennifer Paradise.

ETH.MESH.09142511 to ETH.MESH.09142511 (Draft) EWHU Memo from Bart Pattyson (US Marketing and Professional Education) to US Faculty Members re: Gynecare Prosima - Pelvic Floor Repair System, Updated Professional Education Deck.

ETH.MESH.09144349 to ETH.MESH.09144349 Powerpoint: Ethicon Women's Health and Urology: Clinical Expertise Road Map.

ETH.MESH.09191424 to ETH.MESH.09191426 Email string, top one from Hemangini Patel to Carolina Guzman re: Final Draft report for Prosima - Urgent; cc: Irene Leslie, Rosangela Ribeiro.

ETH.MESH.09207059 to ETH.MESH.09207059 Chart entitled "Grier."

ETH.MESH.09218452 to ETH.MESH.09218453 Email string, top one from Rhonda Peebles to Andrew Meek re: Remaining 2010 labs; cc: Kevin Frost, et al.

ETH.MESH.09238537 - TVT Secur 12 month Post Launch Review

ETH.MESH.09264945-46 - Prolene Mesh Re-Design Project

ETH.MESH.09268043-045

ETH.MESH.09283030 to ETH.MESH.09283030 Spreadsheet re: Open Incontinence & AP.

ETH.MESH.09283031 to ETH.MESH.09283031 Spreadsheet re: Open Incontinence & AP.

ETH.MESH.09283032 to ETH.MESH.09283032 Spreadsheet re: Pelvic Floor Repair

ETH.MESH.09283033 to ETH.MESH.09283033 Spreadsheet re: Budget Summary

ETH.MESH.09283034 to ETH.MESH.09283034 Spreadsheet re: Integrated Marketing

ETH.MESH.09283035 to ETH.MESH.09283035 Spreadsheet re: Summary

ETH.MESH.09283036 to ETH.MESH.09283036 Spreadsheet re: Pelvic Floor Repair

ETH.MESH.09283037 to ETH.MESH.09283037 Spreadsheet re: Budget Summary

ETH.MESH.09283038 to ETH.MESH.09283038 Spreadsheet re: Integrated Marketing

ETH.MESH.09290755 to ETH.MESH.09290755 Spreadsheet re: Q1 2012 Open PO Summary

ETH.MESH.09290760 to ETH.MESH.09290760 Spreadsheet re: Open Incontinence & AP.

ETH.MESH.09290767 to ETH.MESH.09290767 Spreadsheet re: Uterine Health

ETH.MESH.09290769 to ETH.MESH.09290769 Spreadsheet re: Ethicon Gynecare May 2012 Open PO Summary

ETH.MESH.09290772 to ETH.MESH.09290772 Spreadsheet re: Budget Summary

ETH.MESH.09300480 to ETH.MESH.09300480 Spreadsheet re: Prosima All Day

ETH.MESH.09625725 to ETH.MESH.09625729 Government Submissions Log Sheet

ETH.MESH.09625731 to ETH.MESH.09625737 FDA Letter. re: approved drug application for polypropylene suture.

ETH.MESH.09625816 to ETH.MESH.09625816 FDA letter re: receipt of drug application for polypropylene suture.

ETH.MESH.09625817 to ETH.MESH.09625817 Letter to FDA re: new drug application for Polypropylene Suture.

ETH.MESH.09629447 to ETH.MESH.09629448 FDA Labeling Approval for Prolene

ETH.MESH.09630649 - 4.26.1973 FDA Letter RE: NDA 16-374 package insert for Prolene.

ETH.MESH.09634081 to ETH.MESH.09634081 Sections 6 re: adverse effects.

ETH.MESH.09634299 to ETH.MESH.09634303 FDA Letter re: approval of PMA supplement.

ETH.MESH.09634318 to ETH.MESH.09634318 Prolene Package Insert.

ETH.MESH.09634662 to ETH.MESH.09634663 FDA Letter re: reclassification of Nonabsorbable Polypropylene Surgical Suture.

ETH.MESH.09634664-688 FDA Letter re: reclassification of Nonabsorbable Polypropylene Surgical Suture.

ETH.MESH.09656792

ETH.MESH.09656795

ETH.MESH.09744840-45

ETH.MESH.09744848-55

ETH.MESH.09744858-63 - TVT Patient Brochure

ETH.MESH.09746948-998 - License and Supply Agreement [Rosenzweig Exhibit 21 - 12.22.15]

ETH.MESH.09747038-097 - Medscand Agreement

ETH.MESH.09747337-369 - Asset Purchase Agreement

ETH.MESH.09888187-223 - Seven Year Data for Ten Year Prolene Study - Plaintiff's Exhibit 4102

ETH.MESH.09911296-299 - Dan Smith email dated 11.13.2008 re things to consider as we assess next steps for a next generation sling (Engleman/Adkins Trial Exhibit P1676)

ETH.MESH.09922570-578 - R&D Memorandum of PA Mesh Assessments for TVTO-PA Revision 1

ETH.MESH.09951746-747 - Scott Ciarrocca email to Katrin Elbert dated 02.27.2009 re minime discussion at the board meeting (Engleman/Adkins Trial Exhibit P1677)

ETH.MESH.10027307-328 - TVT Surgeons Resource Monograph - June 2000

ETH.MESH.10038839 - Gynemesh PS Slide Deck 2004

ETH.MESH.10038844 - The Use of Graft Material in Prolapse Repair - Dr. Sepulveda

ETH.MESH.10048035-036 Email from Mark Pare to Walter Boldish, et al. re: Clinical #2 - Prosima; cc: Elizabeth David, et al.

ETH.MESH.10179518-636 - Clinical Evaluation Report - Gynemesh PS signed by P. Hinoul on 04.26.2013

ETH.MESH.10179518-636 Clinical Evaluation Report - Gynecare Gynemesh ™ PS Nonabsorbable Prolene ™ Soft Mesh signed by Piet Hinoul April 26, 2013...

ETH.MESH.10220659

ETH.MESH.10224077 - Email string, top one from Molly Dugan to Greg Prine re: Prosima Lab Feedback; cc: Joseph Drabik.

ETH.MESH.10232708 - Email from Stevan Barendse to Greg Prine re: Prosima targets.

ETH.MESH.10281860-874 - Tension-Free Midurethral Sling: Market Update.

ETH.MESH.10376963

ETH.MESH.10378001-8002

ETH.MESH.10384309-310

ETH.MESH.10399553-554 Email from Judi Gauld to Marcus Carey, et al. re: Prosima presentation at AUA; cc: David Robinson, et al.

ETH.MESH.10551392-399

ETH.MESH.10608341-357 Post Market Surveillance Report. Pelvic Floor Repair Systems. Gynecare Prolift, Gynecare Prolift+M and Gynecare Prosima.

ETH.MESH.10608341-57 - Post market surveillance report - litigation spike

ETH.MESH.10608341-57 - Post Market Surveillance Report. Pelvic Floor Repair Systems. Gynecare Prolift, Gynecare Prolift+M and Gynecare Prosima

ETH.MESH.10686760-771 - Gynemesh PS aFMEA 2013

ETH.MESH.10686833-852 - Risk Management Report (RMR) for Gynemesh PS 2013

ETH.MESH.10817931 Pelvic Mesh Post-Market Surveillance Orders April 2012

ETH.MESH.10960414 - Email from Christopher O'Hara to François Barbe, et al. re: VRT for Prosima.

ETH.MESH.10977-983

ETH.MESH.11048537-538 Prosima E-blast No. 1 "The Proof of Success."

ETH.MESH.11335589 - Risk Assessment for TVT Secur 2013.

ETH.MESH.11336474-487 - Ten Year In Vivo Suture Study Scanning Electron Microscopy-5 Year Report - Plaintiff's Exhibit 4111

ETH.MESH.11448841 Conference Participant Report 8/25/11

ETH.MESH.11518663-665 Email string, top one from Melissa Doyle to Arthur Mourtzinos re: Agenda for tomorrow's lab.

ETH.MESH.11522550-551 Email string, top one from Melissa Doyle to Seth Moskos re: VSD "take home" instructions.

ETH.MESH.11523079 - Email from Melissa Doyle to Walter Boldish, et al. re: Lahey Labs September 18, 2010; cc: Carole Carter-Cleaver.

ETH.MESH.11524125-128 Email string, top one from Melissa Doyle to Andrew Meek re: Upcoming Labs - planning.

ETH.MESH.11536046 - Email string, top one from Jonathan Fernandez to Rhonda Peebles re: Remaining 2010 labs; cc: Robert Zipfel, et al.

ETH.MESH.11538048-049 - DX24787 - Frost email re Prosima useage

ETH.MESH.11543641 - Powerpoint GYNECARE GYNEMESH\* PS Nonabsorbable PROLENE\* Soft Mesh Awareness Module

ETH.MESH.11543719 - Robinson Gynemesh PS Presentation Awareness Module 4.7.04

ETH.MESH.11905619 - Spreadsheet: Prosima Virtual Roundtable Calls & Targets

ETH.MESH.1210987-95

ETH.MESH.1222075-79 - Letter to Weisberg/Robinson re: Elongation Characteristics of Laster Cut PROLENE Mesh for TVT, from Kammerer

ETH.MESH.12227301

ETH.MESH.12831391-92 - P4128 - IR Microscopy of Explanted Prolene received from Prof. R. Guidoin.

ETH.MESH.12897617-678 Clinical Evaluation Report - Prosima ™ signed by Piet Hinoul.

ETH.MESH.13204537 - MDD Resolution Form

ETH.MESH.13314554 - Email from Laura Hance to Dr. Lowden re: Prosima answer to JP drain and hydrodissection.

ETH.MESH.13532200 - Ethicon Gynecare WW Commercialization Decision - US Sales Call Script 6/1/12

ETH.MESH.13577809-810 - Prosima Virtual RoundTable

ETH.MESH.13582263 - Reisenauer Prosima study

ETH.MESH.13589382 - Prosima Sales Aid 2

ETH.MESH.13589382 - Prosima Sales Aid 3

ETH.MESH.13589382 - Prosima Selling Guide

ETH.MESH.13592561 - Prosima Trainee Invitation "Advanced Pelvic Floor Course with Gynecare Prosima"

ETH.MESH.13596052 - Prosima Sales Aid 4 (Proof)

ETH.MESH.13600015 - Barber Study - Defining Success After Surgery for POP

ETH.MESH.13618003 to ETH.MESH.13618004 EWHU eClinical Compendium - Article Summary. Reisenauer, C., et al. "Anatomic study of prolapse surgery with nonanchored mesh and a vaginal support device."

ETH.MESH.13618029-031 EWHU eClinical Compendium - Article Summary. Zyczynski, H.M., et al. "One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device."

ETH.MESH.13622000-070 Prosima Trainee Deck Distribution

ETH.MESH.13626471 - Prosima Sales Aid 7 (Proof of Success)

ETH.MESH.13627691 - Expert interview with Dr. Carey (clean)

ETH.MESH.13635675 - 2011 B&W POP & SUI Patient Counseling Guide

ETH.MESH.13635675-696 - Pelvic Organ Prolapse Patient Counseling Guide (2011)

ETH.MESH.13637531 - Prosima presentation background and development history

ETH.MESH.13645631 to ETH.MESH.13645631 DVD - Thoughts on Prolift+M and Prosima from Drs. Michel Cosson and Marcus Carey.

ETH.MESH.13649510 - Prosima Sales Training Program

ETH.MESH.13650207 - Prosima Sales Aid Brochure (Dance)

ETH.MESH.13670432 - Prosima Key Procedural Steps (double-sided)

ETH.MESH.13697383 - Prosima legal manufacturer Ethicon Sarl

ETH.MESH.13698543 to ETH.MESH.13698543 Prosima Marketing Material Roll-Out Letter.

ETH.MESH.13698840-59 - Bart Pattyson editorial re prof ed bulletin

ETH.MESH.13699623 - Prosima sales training points

ETH.MESH.13699656 - Prosima DVD

ETH.MESH.13699656 - Prosima Sales Rep materials

ETH.MESH.13699656 - Prosima video with Van Drie and Grier.wmv

ETH.MESH.13699674 to ETH.MESH.13699754 Clinical Study Report: A Prospective, Multi-centre Study to Evaluate the Clinical Performance of the Gynecare Prosima ™ Pelvic Floor Repair System as a Procedure for Pelvic Organ Prolapse.

ETH.MESH.13713001 - Good image of Prosima box

ETH.MESH.13718001 - Prosima Objective Success Learning Guide

ETH.MESH.13718497 - Prosima Patient Brochure 2

ETH.MESH.13724290 - Prosima Apical Support Learning Guide

ETH.MESH.13726909 - Prosima Key Points

ETH.MESH.13727241 - Prosima Overview Presentation

ETH.MESH.13733674 - Prosima MRI Image and Sales Aid

ETH.MESH.13756212 to ETH.MESH.13756218 Clinical study Finding Discussion for Gynecare Prosima ™ Pelvic Floor Repair System by Piet Hinoul (Audio Transcript).

ETH.MESH.13756219 to ETH.MESH.13756219 Gynecare Prosima ™ Pelvic Floor Repair System MRI Address

ETH.MESH.13756384 to ETH.MESH.13756384 Prosima Virtual Round Table Trainee Confirmation

ETH.MESH.13756409 to ETH.MESH.13756409 Prosima Virtual Round Table Preceptor Follow-up and Invitation.

ETH.MESH.13756416 to ETH.MESH.13756417 Prosima Virtual Round Table Preceptor Confirmation.

ETH.MESH.13869166 to ETH.MESH.13869166 Powerpoint: Mint Project - Pelvic Floor Repair.

ETH.MESH.13907284 - Power Point - Particles in TVT-O Blisters

ETH.MESH.14020602 - Dr. Gregory Bolton email to Kathy Hampton dated 09.05.2007 re TVT Secur (Engleman Trial Exhibit P1769)

ETH.MESH.14415283-86

ETH.MESH.14427453 to ETH.MESH.14427455 FDA Clearance Letter re: K063562 Gynecare Prosima ™

ETH.MESH.14427459 to ETH.MESH.14427543 Letter to FDA re: 510(k) K063562 S1, response to deficiencies email.

ETH.MESH.14427562 to ETH.MESH.14427563 Memo to Prosima Regulatory File. Minutes from Teleconference with FDA for Prosima 510(k).

ETH.MESH.14427564 to ETH.MESH.14427565 FDA Letter re: K063562 Gynecare Prosima Premarket Notification 510(k)

ETH.MESH.14427567 to ETH.MESH.14427569 Email from Nada Hanafi to Patrice Napoda re: K063562 Gynecare Prosima.

ETH.MESH.14427578 to ETH.MESH.14427761 Traditionsl 510(k) Premarket Notification Gynecare Prosima ™ Pelvic Floor Repair System.

ETH.MESH.14901753 - Batch Review Lot #3405428 Complaint PI1

ETH.MESH.15057318 - Dr. David Robinson memo analysis dated 02.23.2006 re elongation characteristics of laser-cut Prolene mesh for TVT Secur

ETH.MESH.15958178-182 Email string, top one from Brian Luscombe to Tom Affeld re: Approved for distribution: FDA Notification FAQS and Customer Letter.

ETH.MESH.161953-54 - Gynecare TVT Obturator System Sales Materials

ETH.MESH.16259973 Email from Lisa Jannone dated 1/5/12 re message from Lesley Fronio re update on recent media reports

ETH.MESH.16262740 (2004)

ETH.MESH.16350627-628 Email string, top one from Piet Hinoul to Paan Hermansson re: key message for upcoming Prosima launch.

ETH.MESH.16352932-934 Email from Paan Hermansson to Sonja Willems, et al. re: Great EWH&U success at ICS/IUGA congress in Toronto; cc: Bernhard Fischer, et al.

ETH.MESH.1751069-94 - 09/07/2009 Safety review: TVT and TVT-O procedures

ETH.MESH.17669942 - Email from Robert Zipfel tp Elizabeth David, et al. re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones and Schlafstein on Monday Jan 4, 2010.

ETH.MESH.17748760-761 E-mail from Kevin Frost regarding 2011 Incontinence & Pelvic Floor Recap

ETH.MESH.1784779-82 - Memo re: TVT-Base & TVT-O Complaint Review for Laser Cut Mesh (LCM) Risk Analysis

ETH.MESH.1784823-28

ETH.MESH.1809056-58

ETH.MESH.1809080-81 - Memo re: Comparison of Laser-cut and machine-cut TVT Mesh to Meshes from Competetive Devices (BE02004-1641)

ETH.MESH.1815660-64 - Project Mulberry, Preliminary Clinical Diligence Report ]

ETH.MESH.18844812 - Email from Patrick Kaminski to Robert Zipfel re: Dr. Thomas Antonini; cc: Stevan Barendse re delaying launch.

ETH.MESH.19308264-265 Email from Walter Boldish to Stefanie Garbarino re: Prosima cadaver labs.

ETH.MESH.19310234-238 Email string, top one from Stefanie Garbarino to Dr. Maxwell re: TVT-O

ETH.MESH.19804279-86

ETH.MESH.222852-63 - 12/15/2003, Gynecare Final Report # 03\*0740, TVT Obturator System

ETH.MESH.222899-909

ETH.MESH.PM.000001 ETH.MESH.PM.000003

**Production Materials** ETH.MESH.2236604-09 - TVT Obturator Brochure; "Results, Precision & Proven Mesh" ETH.MESH.223779-84 - Risk Management Report, TVT Laser Cut Mesh (LCM). Document Number RMR-0000017, Rev. 3 ETH.MESH.22625140-45 - MDD CAPA # CAPA-003474 ETH.MESH.22631022-2029 - TVT - Response to Section 39 Request, D-1, 1-1002 ETH.MESH.2293715-6 ETH.MESH.2340504-33 - TVT IFU ETH.MESH.2340902-8 ETH.MESH.25576110 - 30 Proceed studies from 2016.10.00 Proceed CER Rev. 6 Schmitz.Day.Lin ETH.MESH.262089-123 - Manuscript Draft: (de Leval) Novel surgical technique for the treatment of female stress urinary incontinence: Transobturator Vaginal Tape Inside-Out ETH.MESH.3364663-66 ETH.MESH.3365250-1 ETH.MESH.341006-11 - 11/11/10 Letter from John Young re: Global Regulatory Strategy for TVT IFU (RMC P15506/E) Update (Part II, RA0001-2010, Rev. 1) ETH.MESH.3427878-83 - TVT IFU ETH.MESH.371496-594 - 01/28/98 Letter from FDA re: K974098 TVT System ETH.MESH.3922926-28 ETH.MESH.3932909-11 - History of TVT-O ETH.MESH.3934952-67 - Tension-Free Vaginal Obturator Tape (TVOT) - April 30, 2003 - Meeting Report ETH.MESH.3939167-71 - Waltregny (2006) Inside Out Transobturator Vaginal Tape for the Treatment of Female Stress Urinary Incontinence: Interim Results of a Prospective Study After a 1-Year Minimum Followup ETH.MESH.4048515-20 - KOL Interview ETH.MESH.4384126-65 ETH.MESH.442825-26 ETH.MESH.524746-48 ETH.MESH.525573 ETH.MESH.5315252-65 - Final Report, PSE Accession No. 97-0197, Project No. 16672 ETH.MESH.658177-198 - Surgeon's Resource Monograph, A Report of the June 2000 Summit Meeting ETH.MESH.6696411-19 ETH.MESH.6859834-35 ETH.MESH.6878438-39 - Memo re: VOC on new Laser Cut TVT Mesh ETH.MESH.6882641-642 ETH.MESH.6886410-411 ETH.MESH.7393700 - 05/13/2003 Memo to Gynecare Continence Health Sales Team re: Gynecare TVT Physician Training Policy ETH.MESH.7692905-907 ETH.MESH.8003295-301 - Patient Brochure: "Stop coping, start living." ETH.MESH.8003303-317 - Patient Brochure: "Stop coping, start living." ETH.MESH.823793-806 - Transobturator Vaginal Tape Inside-Out (TVT-O): From Development to Clinical Experience ETH.MESH.865069-72

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### **Production Materials**

ETH.MESH.PM.000004
ETH.MESH.PM.000006
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ETH.MESH.PM.000059
ETH.MESH.PM.000065 - Prolift Professional Education Videos
ETH.MESH.PM.000068
ETH.MESH.PM.000008  ETH.MESH.PM.000075 - Prolift Professional Education Videos
ETH.MESH.PM.000076 - Prolift Professional Education Videos
ETH.MESH.PM.000078 - Prolift Professional Education Videos
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ETH.MESH.PM.000084
ETH.MESH.PM.000087
ETH.MESH.PM.000088 - Anatomy Videos
ETH.MESH.PM.000088 - Anatomy Videos
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ETH.MESH.PM.000090 - Anatomy Videos  ETH.MESH.PM.000092 - Prolift +M Professional Education Videos
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ETH.MESH.PM.000134 - Anatomy Videos
ETH.MESH.PM.000143
ETH.MESH.PM.000145 - Prolift +M Professional Education Videos
ETH.MESH.PM.000148
ETH.MESH.PM.000151 - Anatomy Videos

ETH.MESH.PM.000154 - Anatomy Videos
ETH.MESH.PM.000156
ETH.MESH.PM.000157
ETH.MESH.PM.000170
ETH.MESH.PM.000171
ETH.MESH.PM.000179 - TVT Secur IFU V5e 2005 to disc (Original from Prof Ed DVD)
ETH.MESH.PM.000179 - TVT-Secur Key Tech Points 5.24.2007 (Color Oringinal from Prof Ed DVD)
ETH.MESH.PM.000190 - Prolift Professional Education Videos
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[ETH.MESH.08003231-46] [ETH.MESH.08003247-62] [ETH.MESH.08003263-78] [ETH.MESH.08003279-94]

[ETH.MESH.08003295-302] [ETH.MESH.08003303-18] [ETH.MESH.09744840-ETH.MESH.09744845]

[ETH.MESH.09744848-ETH.MESH.09744855] [ETH.MESH.09744858-ETH.MESH.09744863]

TVT Secur IFU

TVT Secur Professional education

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TV	Γ-Abbrevo	Company	/ Documents
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Deponent [Date of Deposition]
Angelini, Laura [09.16.2013]
Angelini, Laura [09.17.2013]
Angelini, Laura [11.14.2013]
Arnaud, Axel [11.15.12]
Arnaud, Axel [11.16.12]
Arnaud, Axel [7.19.2013]
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Austin, Charles E 08.13.2015
Barbolt, Thomas [1.7.2014]
Barbolt, Thomas [1.8.2014]
Barbolt, Thomas [8.14.2013]
Barbolt, Thomas [8.15.2013]
Barbolt, Thomas Ph.D. [10.10.12]
Barbolt, Thomas Ph.D. [10.9.12]
Batke, Boris [8.1.2013]
Batke, Boris [8.2.2013]
Beach, Patricia [6.17.13]
Beath, Catherine [11.8.12]
Beath, Catherine [11.9.12]
Beath, Catherine [3.26.12]
Beath, Catherine [3.27.12]
Beath, Catherine [7.11.2013]
Beath, Catherine [7.12.2013]
Brown, Allison [9.11.13]
Burkley, Dan F [5.22.2013]
Burkley, Dan F [5.23.2013]
Burkley, Daniel [10.2.12] Cecchini, Peter [10.22.2013]
Cecchini, Peter [10.22.2013] Cecchini, Peter [10.23.2013]
Chahal, Ricky [12.10.2014]
Chen, Meng [10.29.2013]
Chen, Meng [10.23.2013] Chen, Meng [10.3.12]
Chen, Meng [10.30.2013]
Chen, Meng [10.4.2012]
Courts, Paul [6.11.15]
Elbert, Katrin [12.23.14]
Elbert, Katrin, Ph.D. [12.23.2014]
Gauld, Judith [11.8.13] [4.27.12]
Grier, Douglas [12.30.2014]
Hart, James [12.20.13]
Hart, James [9.17.13]
Hart, James [9.18.13]
Hellhammer, Brigitte [9.11.2013]
Hellhammer, Brigitte [9.12.2013]
Hinoul, Piet - 01.13.2014 Deposition Testimony
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Hinoul, Piet - 06.26.2013 Deposition Testimony
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Hinoul, Piet M.D., Ph.D. [4.5.12]
Hinoul, Piet M.D., Ph.D. [4.6.12]
Hinoul, Piet M.D., Ph.D. [9.18.12]
Hinoul, Piet M.D., Ph.D. [9.19.12]
Holste, Joerg [12.14.12]
Holste, Joerg [12.15.12]
Holste, Joerg [7.29.2013]
Holste, Joerg [7.30.2013]
Horton, Ronald, M 07.01.2015
Isenberg, Richard [11.05.2013]
Isenberg, Richard [11.06.2013]
Jones, Gregory R [8.20.2013]
Kammerer, Gene [01.17.2014]
Kammerer, Gene [01.28.2014]
Kammerer, Gene [01.30.2014]
Kammerer, Gene [10.17.12]
Kammerer, Gene [12.03.2013]
Kammerer, Gene [12.05.2013]
Kammerer, Gene [6.12.2013]
Kanerviko, Brian [8.23.13] [8.22.13]
Kirkemo, Aaron [01.06.2014]
Kirkemo, Aaron [01.07.2014]
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Lamont, Daniel [5.24.12]  Lamont, Daniel [5.24.12]
Lin, Susan [3.12.2013]
Lin, Susan [3.13.2013]
Lin, Susan [5.2.2013] Lin, Susan [5.2.2013]
Lin, Susan [5.3.2013] Lin, Susan [5.3.2013]
Lin, Susan [8.1.2013]
Lisa, Bryan [12.19.11]
Lisa, Bryan [12.20.11] Lisa, Bryan [12.20.11]
Lisa, Bryan A [4.25.2013]
Lisa, Bryan A [4.26.2013]
Luscombe, Brian [7.29.13]
Mahmoud, Ramy [7.15.2013]
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Nager, Charles - 06.10.2014 Deposition Testimony
Owens, Charlotte [6.19.2013]
Owens, Charlotte [6.20.2013]
Owens, Charlotte M.D. [9.12.12]
Owens, Charlotte M.D. [9.13.12]
Parisi, Paul [6.6.13]
Peebles, Rhonda [07.16.2014]
Peebles, Rhonda [07.16.2014] Peebles, Rhonda [08.20.2014]
Robinson, David [7.24.2013]
Robinson, David [7.25.2013]
Robinson, David [9.11.2013]
Robinson, David M.D. [3.13.12]
Robinson, David M.D. [3.14.12]
Robinson, David M.D. [8.23.12]
Schmid, Tim - 07.31.2015
Selman, Renee Elayne [6.20.2013]
Selman, Renee Elayne [6.21.2013]
Smith, Dan J [2.3.2014]
Smith, Dan J [2.4.2014]
Smith, Dan J [5.15.2013]
Smith, Dan J [5.16.2013]
Smith, Dan J [6.4.2013]
Smith, Dan J [6.5.2013]
Smith, Dan J [8.20.2013]
Smith, Dan J [8.21.2013]
St Hilaire, Price [7.11.13]
Vailhe, Christophe [6.20.13]
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Weisberg, Martin - 05.24.2012 Deposition Testimony
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Weisberg, Martin [5.30.2013]
Yale, Mark [4.17.12]
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AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence (2011)

AUA Position Statement POP (2011) - Position Statement on the Use of Vaginal Mesh for the Repair of POP

AUA SUI Guidelines (2012 Update) - Appendices A11 and A16 (regarding Complications)

AUA Urinary Incontinence. Updated August 2012

AUA. Position Statement on the Use of Vaginal Mesh for the Repair of Pelvic Organ Prolapse. November 2011; reaffirmed October 2016 and October 2018

**AUA-SUI Pocket Guide for Physicians** 

AUGS Position Statement - March 2013 - Position Statement on Restrictions of Surgical Options for Pelvic Floor Disorders

AUGS Position Statement on Restrictions of Surgical Options for Pelvic Floor Disorders

**AUGS Residency Guidelines** 

**AUGS Resident Learning Objectives** 

AUGS SUFU Frequently Asked Questions by Patients MUS for SUI

AUGS SUFU Frequently Asked Questions by Providers MUS for SUI

AUGS SUFU Position Statement on MUS for SUI

AUGS, SGS Oral Poster 55 - A Clinical Assessment of Gynemesh PS for the Repair of Pelvic Organ Prolapse (2004)

AUGS/ACOG Committee Opinion No. 601, June 2014: Evaluation of Uncomplicated Stress Urinary Incontinence in Women Before Surgical Treatment

AUGS/SUFU FAQs for Patients and Providers re MUS for SUI (2014 Mar 12)

AUGS/SUFU Frequently Asked Questions by Patients: Mid-urethral slings for stress urinary incontinence (March 12, 2014)

AUGS/SUFU Frequently Asked Questions by Providers: Mid-urethral slings for stress urinary incontinence (March 12, 2014)

AUGS/SUFU Position Statement on Mesh Mid-urethral Slings for Stress Urinary Incontinence (approved 1.3.2014)

AUGS: Blogs: Organizations Lend their Support to Mid-urethral Slings

AUGS: Position statement on the restriction of surgical options for pelvic floor disorders

AUGS-SUFU MUS Position Statement updated June 2016

Barber Summary Positioning Prosima- Ethicon Women's Health & Urology eClinical Compendium- Article Summary [3 pages]

Boukerou Summary Positioning Prosima- Ethicon Women's Health & Urology eClinical Compendium- Article Summary [3 pages]

Clinical Study Findings Discussion for GyneCare Prosima™ Pelvic Floor Repair System by Piet Hinoul PROS-436-10-9/12- Prosima Audio File of 2 year Data [7 pages]

Code of Federal Regulations Title 21, as of 4/1/15. 21CFR801.109

Color Version of SUI Patient Counseling Guide (no bates labels)

Committee on Practice Bulletins-Gynecology, American Urogynecologic Society. Practice Bulletin No. 185: Pelvic Organ Prolapse. Obstet Gynecol. 2017 Nov; 130(5): e234-e250.

Committee Opinion No. 694: Management of Mesh and Graft Complications in Gynecologic Surgery. Obstet Gynecol. 2017 Apr;129(4):e102-e108. Committee Opinion No. 694 Summary: Management of Mesh and Graft Complications in Gynecologic Surgery. Obstet Gynecol. 2017 Apr;129(4):773-774.

Communications within the pelvic floor surgical community in 2008, 2011 and 2012 relating to the FDA notices, committee meetings, orders and other developments concerning the use of synthetic mesh and other surgical approaches to pelvic organ prolapse repair

Defense Cross of Weber Slide 12.08.15 Retracted Statement Regarding Nature of POP Surgery

Device Labeling. 21 CFR 801.109(c)

Documents proposed by Plaintiff's counsel to be stipulated to as business records

DVD- Thoughts on Gynecare Prolift+M™ and Gynecare Prosima™ from Drs. Michel Cosson and Marcus Carey

EAU Guidelines on Urinary Incontinence (Partial Update March 2015)

EU Commission Fact Sheet - (based on 2015 SCENIHR Report) The safety of surgical meshes used in Urogynecological surgery.

Excerpts from Budke trial transcript (Day 4, 01.08.2015).

FDA 2013 Mar - Considerations about Surgical Mesh for SUI

FDA 24-Hour Summary: Obstetrics & Gynecology Devices Panel (September 8-9, 2011)

FDA Considerations about Surgical Mesh for SUI [03.27.2013].

FDA Device Labeling Guidance #G91-1 March 1991

FDA Device Labeling Guidance Blue Book March 1991

FDA Executive Summary: Reclassification of Urogynecologic Surgical Mesh Instrumentation 2.26.2016

Gastroenterology-Urology Medical Devices Advisory Committee Panel

FDA Executive Summary: Surgical Mesh for Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence - Obstetrics & Gynecology Devices Advisory Committee Meeting (September 8-9, 2011)

FDA Information on Surgical Mesh for Hernia Repairs (2008)

FDA Information on Surgical Mesh for Pelvic Organ Prolapse and Stress Urinary Incontinence (2008)

FDA News Release: Surgical Placement of mesh to repair pelvic organ prolapse poses risk [07.13.2011].

FDA Position Statement regarding considerations about surgical mesh for SUI (March 27, 2013)

FDA Presentation: FDA Perspective on Surgical Mesh for Stress Urinary Incontinence (September 9, 2010 - Gaithersburg, MD)

FDA Public Health Notification - 2008 Oct. 20

FDA Public Health Notification - 2011 July 11

FDA Public Health Notification - Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence (2008)

FDA Public Health Notification. 2008.

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/

FDA Public Health Notification. 2011.

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.

FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surigical Mesh in Repair of POP and SUI. Issued: 10.20.2008.

FDA Questions: Reclassification of the Urogynecologic Surgical Mesh Instrumentation.

FDA response to 522 Plan Apr 2 2012

FDA response to Discontinuation Plan

FDA Safety Communication 7.13.11 - Update on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse

Gynecare Prosima Clinical Study Investigator Meeting Qualitative Feedback Analysis [15 pages]

Gynecare Prosima content for ethicon360.com [5 pages]

Gynecare Prosima updates to ethicon360.com PROS-314-11-8/12 [113 pages]

Gynecare Prosima VSD Patient Brochure 2009: Stop Coping, Start Living. [2 pages]

Gynecare Prosima VSD Patient Information Slim-Jim: What you should know about the Gynecare Prosima Vaginal Support Device; Stop Coping. Start living™ [2 pages]

Gynecare Prosima™ AIDiNC Selling Guide- Your Guide to Selling Gynecare Prosima™ with the AIDiNC process [16 pages]

Gynecare Prosima™ Pelvic Floor Repair System MRI Address PROS-437-10-9/12- Prosima Audio File of MRI Flashcard [1 page]

Gynecare Prosima™ Pelvic Floor Repair System- Objective Success Learning Guide & Key Steps for Success [37 pages]

Gynecare Prosima™ Pelvic Floor Repair System Preceptorship Invitation [1 page]

Gynemesh PS white paper

http\_\_\_www.voicesforpfd - AUGS Patient Information: Mesh Information for Patients with Pelivic Floor Disorders

#### ICS Fact Sheet 2015

International Urogynecological Assocation: The Usage of Grafts in Pelvic Reconstructive Surgery Symposium 2005 July 8-10, 2005, Lago Mar Resort, Fort Lauderdale, FL, USA. Int Urogynecol J 2006; 17: S1-55

IUGA Anterior Vaginal Repair (Bladder Repair)

IUGA Brochure: Vaginal repair with mesh.

IUGA Guidelines for training in FPMRPS; Updated 2010

IUGA Mid-urethral sling (MUS) procedures for stress incontinence (2011)

IUGA Position Statement on MUS for SUI (2014)

IUGA Poster - Clinical experience of a novel vaginal support device and balloon used to simplify mesh augmented vaginal surgery for prolapse. (Slack, M.)

IUGA Posterior Vaginal Wall and Perineal Body Repair

IUGA Sacrocolpopexy: A guide for women

IUGA/ICS Joint Terminology and Classification of the Complications related directly to the insertion of prostheses (Meshes, implants tapes) & Grafts in female pelvic floor surgery. [38 pages]

Lucente, V. Pelvic Organ Prolapse Poster. AUGS 2004.

Lucente, V., et al. Medium-Term Clinical Outcomes Following Trocar-Guided Mesh Repair of Vaginal Prolapse Using Partially Absorbable Mesh. AUGS Abstract. Submitted 4/5/2012)

Oxford Levels of Evidence Pyramid for Practitioners from Oxford Website http://www.cebi.ox.ac.uk/for-practitioners/what-is-good-evidence.html

Presidents Letter: President's Perspective: Organizations Lend their Support to Mid-urethral Slings.

RANZCOG Position statement on midurethral slings (May 2017)

RANZOG and UGSA 2014 Position Statement

Reclassification of Urogynecologic Surgical Mesh Instrumentation FDA Questions - Gastroenterology and Urology Devices Panel of Medical Devices Advisory Committee 2.26.2016

The FDA and Mesh, What You Should Know as a Reconstructive Pelvic Surgeon by Lucente, V.; Cassidenti, A.; Culligan, P. White Paper Dated February 9, 2016

The King's Health Questionnaire. Linda Cardozo and Con Kelleher, 1997

Update AUA (2012) -SUI Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update - Appendices A11 and A16 (re Complications)

#### Other

Boukerou Summary Positioning Prosima- Ethicon Women's Health & Urology eClinical Compendium- Article Summary [3 pages]

Corporate Product Characterization Plan, TVT-Laser Cut Mesh. Dated 02/06/2006.

Demonstrative - Ethicon Powerpoint - Almost uniformly, physicians did not express a preference for company name (Engleman trial exhibit)

Demonstrative - Ethicon powerpoint - Next generation slings - evaluating opportunities, considering risks (Engleman trial exhibit)

Demonstrative - Powerpoint - Warning regarding FBR inflammatory response (pgs 18, 22-27)(Engleman trial exhibit)

Deposition Subject Matter-Design and Development of Mesh Products

**Device Labeling Guidance** 

Gynecare Prosima™ Pelvic Floor Repair System- Objective Success Learning Guide & Key Steps for Success [37 pages]

Prosima 2011 Sales Aid- What Could a Truly Tension-Free Repair Mean for you and your Patients? [20 pages]

## Case 3:20-cv-00851-MO Document 249-6 Filed 06/02/22 Page 256 of 259 Douglas Grier Materials List

#### Other Materials

Prosima 522 Order

Prosima Apical Support Learning Guide [2 pages]

Prosima E-Blast No. 1- The Proof of Success [2 pages]

Prosima Launch Sales Aid- Your Proof: Her dance class [3 pages]

Prosima Marketing Material Roll-out Letter from Kevin Forst PROS-040-10-2/12 February 16, 2010 [1 page]

Prosima MRI Flashcard 2- Gynecare Prosima™ Pelvic Floor Repair System. The first fixationless mesh system that maintains anatomical position. [2 pages]

Prosima MRI Flashcard- MRI Flashcard Learning Guide [2 pages]

Prosima NTM Opening Presentation 2011- "This Year Prosima is Personal" [8 pages]

Prosima Pelvic Model

Prosima Preceptor Confirmation- Virtual Round Table October 2010 [2 pages]

Prosima Preceptor Follow Up and Invite-Virtual Round Table October 2010 [1 page]

Prosima Prof Ed Deck 2011 [71 pages]

Prosima Prof Ed Deck 2011 [71 pages]

Prosima Prof Ed Deck October 2009 [21 pages]

Prosima Revised Webinar Deck- [21 pages]

Prosima Sales Aid Training Deck- "What could a truly tension-free repair mean for you and your patients?" [5 pages]

Prosima Testimonal for NTM 2010 Video

Prosima Touch Workshop Key Takeaway [2 pages]

Prosima Trainee Confirmation- Virtual Round Table October 2010 [1 page]

Prosima Trainee Invite- Advanced Pelvic Floor Course with Gynecare Prosima Saturday, October 24, 2009 [1 page]

Reisenauer Summary Positioning Prosima- Ethicon Women's Health & Urology eClinical Compendium- Article Summary [2 pages]

**Testimonial Videos** 

TVT & TVT-O Long Term Studies (94 pages)

Video titled Prosima Shortened Procedure. Hydrodissection and Dissection.

Video: 2010 Prosima Testimonial for NTM

**Wound Closure Manual** 

Zycynski Summary Positioning Prosima- Ethicon Women's Health & Urology eClinical Compendium- Article Summary

Rosenzweig, Bruce, M.D. - 7.14.17 (de bene esse TVT-S deposition)

Rosenzweig, Bruce, M.D. - 7.15.17 (de bene esse TVT-S deposition)

Rosenzweig, Bruce, M.D. - 7.16.17 (de bene esse TVT-S deposition)

Rosenzweig, Bruce, M.D. - 7.17.17 (de bene esse TVT-S deposition)

### **MDL Wave Cases**

Depositions Blaiwas, Jerry (Edwards TVT-O) - 3.28.2014 Blaiwas, Jerry (Farrell Prolift) - 08.13.2015 Blaiwas, Jerry (TVT General Plaintiff Expert) - 03.02.2016 Blaiwas, Jerry (TVT General) 9.24.2015 Blaiwas, Jerry (TVT General) 9.24.2015 Blaiwas, Jerry (TVT-Deneral) 9.24.2016 Blaiwas, Jerry (TVT-Deneral) 9.24.2016 Blaiwas, Jerry (TVT-Deneral) 9.24.2016 Blaiwas, Jerry (Mneeler-Graham Plaintiff Expert) - 03.03.2016 Blaiwas, Jerry (Mneeler-Graham Plaintiff Expert) - 03.18.2016 Elliott, Daniel (Bellew Prolift) - 9.13.2014 Elliott, Daniel (Gross/Wicker/N) Prolift) 11.15.12 Elliott, Daniel (Gross/Wicker/N) Prolift) 11.15.12 Elliott, Daniel (Gross/Wicker/N) Prolift) 11.15.12 Elliott, Daniel (TVT-O General) 9.26.2015 Elliott, Daniel (TVT-O General) 3.6.16 Elliott, Daniel (Expert) 3.6.12 Elliott, Daniel (	
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